Requesting USAID Approval to Procure HIV Test Kits and Other HIV/AIDS-Related Pharmaceutical Products: Guidance and Sources of Information

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Abstract

This guidance document aims to assist USAID Missions and USAID-funded cooperating agencies (CAs) in preparing requests for USAID approval to procure HIV/AIDS-related pharmaceutical products. Consequently, it should help improve the completeness of submitted requests, thus reducing the time taken to process and approve them. Key aspects of USAID procurement guidelines and policies, especially as they relate to the procurement of pharmaceutical products, are described and explained. The document provides detailed guidance to USAID Missions and CAs on preparing such requests and also suggests sources of information to support these requests. Although this guidance document has been specifically developed to support USAID Mission and CA staff who prepare requests for approval to procure HIV/AIDS-related pharmaceutical products for HIV/AIDS programs using USAID funding, Cognizant Technical Officers, Contracting Officers, and Agreement Officers who are assigned to manage the contracts/agreements/grants between USAID and CAs may also find this document a useful resource.

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Acknowledgments

Acronyms

ADS	Automated Directives System [USAID]
AIDS	acquired immune deficiency syndrome
AO	Agreement Officer
BHR/OFDA	Bureau of Humanitarian Response, Office of Foreign Disaster Assistance [USAID]
CA	cooperating agency
CBER	Center for Biologics Evaluation and Research [FDA]
CDC	U.S. Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research [FDA]
CFR	Code of Federal Regulations
CIP	Commodity Import Programs
CO	Contracting Officer
CTO	Cognizant Technical Officer
DS	double-strength
ELISA	enzyme-linked immunosorbant assay
FDA	U.S. Food and Drug Administration
GMP	Good Manufacturing Practice
HIV	human immunodeficiency virus
HIV-1	human immunodeficiency virus type 1
HIV-1-O	human immunodeficiency virus type 1 group O
HIV-2	human immunodeficiency virus type 2
HTLV	human T-lymphotropic virus
MOH	ministry of health
M/OP	Management Bureau, Office of Procurement [USAID]
M/OP/COM	Management Bureau, Office of Procurement, Commodities Division [USAID]
M/OP/TC/COM	Management Bureau, Office of Procurement, Transportation and Commodities Section, Commodities Division [USAID]
MSH	Management Sciences for Health
OI	opportunistic infection
OTC	over the counter
PhRMA	Pharmaceutical Research and Manufacturers of America [U.S.]
Rx	prescription only
smz/tmp	sulfamethoxazole/trimethoprim
RPM	Rational Pharmaceutical Management (Project)
RPM Plus	Rational Pharmaceutical Management Plus (Program)
STD	sexually transmitted disease
SUDS	Single Use Diagnostics System
U.S.	United States of America
USAID	U.S. Agency for International Development
U.S.G.	U.S. government
VCT	voluntary counseling and testing
WHO	World Health Organization

Glossary

Efficacy	**Efficacy** is the ability of a drug or a pharmaceutical product to produce a purported effect as determined by scientific methods.
FDA approval	**FDA approval** means that the product has met the standards of the U.S. Food and Drug Administration (FDA) for safety, efficacy, and quality for the proposed application. Nonprescription drugs that meet the FDA standards for safety, efficacy, and quality can be either FDA-approved or covered by a final over-the-counter monograph. For the purposes of this guidance document, FDA-approved products include nonprescription products that are covered by a final over-the-counter monograph.
Origin	The **origin** of a pharmaceutical product is the country in which it is produced.
Pharmaceutical products	**Pharmaceutical products** include drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents and test kits (including HIV test kits and antibiotic susceptibility testing kits) for the purpose of USAID procurement regulations.
Quality	The **quality** of a pharmaceutical product is determined by its identity, purity, potency, uniformity of dosage form, bioavailability, and stability.
Safe medical product	FDA defines a **safe medical product** as one that has reasonable risks given the magnitude of the benefit expected and the alternatives available.
Sensitivity	**Sensitivity** of a test is the probability of testing positive if infection or disease is truly present. As the sensitivity of a test increases, the number of false negatives decreases.
Source	The **source** of a product is the country a commodity is shipped from and does not include free ports or bonded warehouses. The source can be the cooperating country, if that is where the commodity is located at the time of purchase.
Specificity	**Specificity** of a test is the probability of testing negative if infection or disease is truly absent. As the specificity of a test increases, the number of false positives decreases.

Part I

USAID Procurement Requirements

Chapter 1

Introduction

Section A

Why has this guidance document been written?

In 2000, the U.S. Agency for International Development (USAID), Division of HIV/AIDS, requested assistance from the Rational Pharmaceutical Management (RPM) Project to review the guidelines and procedures for USAID-funded procurement of HIV/AIDS-related pharmaceutical products. RPM findings and recommendations are outlined in a report titled *USAID-Funded Procurement of HIV/AIDS-Related Pharmaceutical Products: Constraints and Options for Improvement*. As part of the review, RPM conducted key informant interviews with staff from USAID Missions and cooperating agencies (CAs) working on HIV/AIDS programs and with staff from the USAID Global Bureau Center for Population, Health and Nutrition. During those interviews, informants identified the lack of guidance material to assist USAID Missions and CAs in preparing requests for approval to procure HIV/AIDS-related pharmaceutical products as a major deficiency, particularly for products that are not approved by the U.S. Food and Drug Administration (FDA) and/or are of non-U.S. source/origin. In addition, one of the most frequent reasons cited by the Management Bureau, Office of Procurement, Transportation and Commodities Section, Commodities Division (M/OP/TC/COM) for the delays encountered in processing requests for approval was the omission or incompleteness of supporting documentation.

The goal of this reference document is to assist USAID Missions and CAs in preparing requests for USAID approval to procure HIV/AIDS-related pharmaceutical products, and as a consequence, to improve the completeness of submitted requests and thus reduce the time taken to process and approve them.

The specific objectives are to—

1. Describe and explain key aspects of USAID procurement guidelines and policies, especially as they relate to the procurement of pharmaceutical products

2. Detail the procedure to obtain USAID approval to procure pharmaceutical products

3. Provide guidance to USAID Missions and CAs on preparing requests for USAID approval to procure HIV/AIDS-related pharmaceutical products

4. Outline sources of information to support requests for approval

Section B

Who is the guidance document for?

This reference document has been specifically developed to support USAID Mission and CA staff who prepare requests for approval to procure HIV/AIDS-related pharmaceutical products for HIV/AIDS programs using USAID funding. Drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents and test kits (including HIV test kits and antibiotic susceptibility testing kits) are all classified as pharmaceutical products for the purposes of USAID regulations.

In addition, USAID Mission/CA staff can apply the framework set forth in this document in preparing requests for USAID approval to procure pharmaceutical products other than HIV/AIDS-related products. Cognizant Technical Officers (CTOs), Contracting Officers (COs), and Agreement Officers (AOs), who are assigned to manage the contracts/agreements/grants between USAID and CAs, may also find this guidance document a useful resource.

Section C

What is in the guidance document?

Do not be put off by the length of this document. Part I contains the specific information on USAID procurement requirements and on the process to follow in preparing a request for approval. Part II, Sources of Information and Assistance, and the annexes make up the majority of the document, and you need only refer to them as necessary. A summary of the remaining chapters follows.

Part I: USAID Procurement Requirements

Chapter 1. Introduction

Chapter 2. USAID Procurement: The Legal and Regulatory Framework

USAID procurement regulations and policies are outlined and explained, and the legislation that underpins these

regulations and policies is described. Existing source/origin waivers and the criteria under which they can be used are described. The implications of USAID procurement regulations and policies for USAID Missions and CAs as procurers of pharmaceutical products are discussed.

Chapter 3. Obtaining USAID Approval to Procure Pharmaceutical Products: The Process

A flowchart presents an overview of the approval process, and specific roles and responsibilities are outlined. Each stage of the process to prepare a request for approval to procure pharmaceutical products is then described in detail and cross-referenced to Chapter 5, Sources of Information and Assistance. Checklists are provided to ensure that all relevant information has been included before a request is submitted for approval. Procedures for tracking requests for approval and applying for amendments to previously approved requests are described at the end of this chapter.

Part II: Sources of Information and Assistance

Chapter 4. Frequently Asked Questions

This chapter contains answers to some frequently asked questions.

Chapter 5. Sources of Information and Assistance

This chapter contains sources of information and assistance cross-referenced from the relevant sections in Chapter 3.

What is **NOT** in this document?

- Information specific to individual contracts/agreements/ grants (contact your CO/AO/CTO for guidance).
- Guidance on financial reporting to USAID.
- Information on the procedure for procuring pharmaceutical products after USAID approval has been received.
- Recommendations on the selection of specific products or specific manufacturers and suppliers. Any supplier or product information is included in this document for purposes of illustration only and does not imply that those suppliers or products are endorsed or preferred over others by USAID or the Rational Pharmaceutical Management Plus (RPM Plus) Program.

This guidance document addresses only the process to obtain approval to procure pharmaceutical products using USAID funding, and that approval is only one step in the procurement process.

Section D

How should this guidance document be used?

- Check with your CTO that the information included in this document is still current. Request information on applicable source/origin waivers that have been approved since this document was written.
- Read all sections of Chapter 2 and Sections A and B of Chapter 3. Look through Chapter 4 to see if any answers to frequently asked questions are immediately relevant to you.
- Consult with your CO/AO and CTO to decide whether to procure pharmaceutical products for your program using USAID funding. Determine if you will need to procure non–U.S. source/origin and/or non-FDA-approved products.
- Plan the process to prepare the request for approval and allocate responsibilities.
- Use Chapter 3, Section C, to prepare the request. Refer to Chapter 5, Sources of Information and Assistance, and Chapter 4, Frequently Asked Questions, as necessary. Use the sample requests in Annexes 8 and 9 as a framework, if desired.
- Refer to Chapter 3, Section D, on how to track your request.
- If applying for amendments to previously approved requests, refer to Chapter 3, Section E.

Chapter 2

USAID Procurement: The Legal and Regulatory Framework

In this chapter, USAID procurement regulations and policies are outlined and explained. Information is given on where to find the USAID regulations and policies relevant to pharmaceutical procurement, and the legislation that underpins these regulations and policies is described. Existing source/origin waivers relevant to the procurement of HIV/AIDS-related pharmaceutical products and the criteria under which they can be used are outlined. Finally, the implications of USAID procurement regulations and policies for USAID Missions and CAs as procurers of pharmaceutical products are described.

Section A

What are the regulations and policies and where can they be found?

USAID's procurement regulations and policies for pharmaceutical procurement are published in the Automated Directives System (ADS) Chapter 312 Eligibility of Commodities and volume 22 of the *Code of Federal Regulations* (22 CFR) Part 228: Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID.

1. Automated Directives System

The Automated Directives System sets out USAID's policies and essential procedures as well as supplementary informational references. It contains six functional series, interim policy updates, valid USAID Handbook chapters, a resource library, and a glossary. The functional series consist of ADS chapters that have been written in a standardized form. Major Functional Series 300: Acquisition & Agreement has superseded USAID Handbook chapter 3.

ADS 312 Eligibility of Commodities can be found at **www.info.usaid.gov/pubs/ads/300/312.htm** [accessed December 20, 2001]. The relevant sections are summarized in Annex 1 and reprinted in Annex 2.

2. Code of Federal Regulations

The CFR is a codification of the general rules and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government.

22 CFR Part 228, Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID, can be found at **www.access.gpo.gov/nara/cfr/waisidx_00/22cfr228_00.html** [accessed December 20, 2001]. The relevant sections are summarized in Annex 1 and reprinted in Annex 3.

Section B

What do the regulations and policies mean?

The sometimes overlapping USAID regulations and policies that are relevant to USAID-funded procurement of pharmaceutical products outline requirements for assuring safety, efficacy, and quality; "Buy America"; and the protection of U.S. patents.

1. Pharmaceutical products

Pharmaceutical products include drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents and test kits (including HIV test kits and antibiotic susceptibility testing kits) for the purposes of USAID procurement regulations.

2. Safety, efficacy, and quality

Pharmaceutical products procured with USAID funding must be FDA approved or information must be available to attest to their safety, efficacy, and quality. FDA approval means that the product has met the standards of the U.S. Food and Drug Administration for safety, efficacy, and quality for the proposed application. For the purposes of this document, FDA-approved pharmaceutical products also include nonprescription pharmaceuticals that are covered by a final over-the-counter monograph.

Procurement of non-FDA-approved pharmaceutical products must be approved by M/OP/TC/COM prior to financing the procurement. To obtain approval to procure non-FDA-approved pharmaceutical products using USAID funding, USAID Missions and CAs must satisfy M/OP/TC/COM that procurement of an FDA-approved product has been considered, if available, and justify the necessity to procure a non-FDA-approved product. Information must also be

submitted to attest to the safety, efficacy, and quality of non-FDA-approved products.

In addition, the Management Bureau, Office of Procurement (M/OP) must be satisfied that the product, whether FDA-approved or not, is correct or appropriate for the proposed application in the specific conditions for which it will be used. Issues that need to be addressed include the following:

- Capacity of the staff to manage and use the product correctly
- Compatibility of the product with those supplied by other donors
- Availability of protocols for the product's use
- Storage and environmental conditions in the cooperating country

3. "Buy America"

The United States is the preferred source and origin of pharmaceutical products procured with USAID funding. The source of a product is the country a commodity is shipped from and does not include free ports or bonded warehouses; the source can be the cooperating country, if that is where the commodity is located at the time of purchase. The origin of a pharmaceutical product is the country in which it is produced.

Under the "Buy America" regulations, USAID Missions and CAs must satisfy M/OP that procurement from a U.S. source and origin has been considered and must justify the need to procure the non–U.S. source and/or non–U.S. origin pharmaceutical product. Exceptions to the U.S. source and origin procurement rule can be made if the following criteria are fulfilled:

1. The pharmaceutical product is essential to the activity.

   and

2. The product in the same or substantially equivalent form is not available from the United States **or** the delivered price from the United States would be at least 50 percent more than from another source.

and

3. Information is available to attest to the safety, efficacy, and quality of the product **or** the product meets the standards of the FDA or other controlling U.S. authority.

and, if applicable

4. It is necessary to procure from a non-U.S. source in order to promote efficiency in the use of U.S. foreign assistance resources including avoiding impairment of foreign assistance objectives.

M/OP/TC/COM advises that the exemption for individual transactions not exceeding $5,000 (excluding transportation) not requiring a source/origin waiver does not apply to restricted commodities, which include pharmaceutical products.

4. Protection of U.S. patents

Exceptions to the U.S. source/origin rule cannot be made if the pharmaceutical product is covered by a current U.S. patent unless "express authorization" is obtained from the patent holder. This requirement cannot be waived.

Section C

What legislation underpins these regulations and policies?

1. Safety, efficacy, and quality

These policies are underpinned by administrative and procedural obligations to ensure that USAID finances the procurement of only safe, efficacious products that are manufactured in accordance with accepted quality standards.

2. "Buy America"/patent protection

USAID procurement regulations and policies are underpinned by statutory obligations under the Foreign Assistance Act (FAA) and the Federal Acquisition Regulations (FARs) and, therefore, are neither discretionary nor easily changed. These statutes promote U.S. trade interests, including those of the U.S. pharmaceutical sector, and protect U.S. patents.

Section D

Source/origin waivers

As of January 2002, two source/origin waivers exist that are relevant to the procurement of HIV/AIDS-related pharmaceutical products. The first applies to the procurement of selected pharmaceuticals for sexually transmitted diseases (STDs) and opportunistic infections (OIs), and the second to HIV test kits. As stated in the December 19, 2000, Action Memorandum, Procurement and Assistance Procedures for HIV/AIDS and Infectious Disease Initiatives, USAID is continuing to review the technical feasibility of procurement of some pharmaceuticals, testing kits, and condoms from non-U.S. sources. Therefore, check with your CTO/AO/CO to see if any source/origin waivers have been approved in addition to the two discussed in Sections D1 and D2.

1. Source/origin waiver for selected pharmaceuticals for STDs and OIs

In December 1997, a source/origin waiver was approved for selected pharmaceuticals procured under the HIV/AIDS Results Package for the treatment of sexually transmitted diseases and specific opportunistic infections. The source/origin waiver allows Geographic Code 935[1] (Special Free World) to be an authorized source/origin for pharmaceutical products in addition to Geographic Code 000 (United States), provided that certain criteria are met.

All pharmaceuticals proposed for Code 935 procurement under the HIV/AIDS Results Package source/origin waiver must conform to the following ADS 310 and 312 and 22 CFR requirements.

1. The pharmaceutical product is essential to the activity.

2. The product in the same or substantially equivalent form is not available from the United States or the delivered price from the United States would be at least 50 percent more than from another source.

3. Information is available to attest to the safety, efficacy, and quality of the product, or the product meets the standards of the U.S. FDA or other controlling U.S. authority.

[1] See Annex 4 for USAID geographic codes.

4. Procurement from a non-U.S. source is necessary in order to promote efficiency in the use of U.S. foreign assistance resources, including avoiding impairment of foreign assistance objectives.

5. No U.S. patent is violated by the purchase of the non-U.S. pharmaceutical product.

All requests for Geographic Code 935 procurement under this waiver must be reviewed and approved by M/OP prior to initiating any procurement. (This source/origin waiver is included as Annex 5.) In addition, all requests for procurement of non–U.S. origin products and/or non-FDA-approved products must be reviewed by MOP/OP/TC/COM. The procurement from Code 935 countries of non–U.S. source products that are of U.S. origin and FDA approved must be reviewed by the AO/CO but do not require MOP/OP/TC/COM review.

2. Source/origin waiver for HIV test kits

USAID Action Memorandum dated January 11, 2001, HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits), is included as Annex 6 and it is also available at **http://www.usaid.gov/pubs/ads/300/updates/iu3-0101.doc.** The source/origin waiver allows Geographic Code 935 (Special Free World) to be an authorized source/origin in addition to Geographic Code 000 (United States) for selected HIV test kits listed in Tab 1 to the memorandum. Annual reviews will determine the adequacy of the waiver authorities and their continuing need. The list is to be updated as new or improved kits become available from U.S. or Geographic Code 935 sources that meet USAID program requirements.

The source/origin waiver applies to all sources of funds, including prior year funds, and to all countries and regions where USAID is pursuing the broad objectives outlined in the HIV/AIDS and Infectious Disease Strategy (Tab A in Action Memorandum of December 19, 2000, Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives, included as Annex 7 and available at **http://www.usaid.gov/pubs/ads/300/updates/iu3-0101.doc**). The source/origin waiver is in effect through 2007 unless terminated before then by agency notice.

Requests for Geographic Code 935 procurement under this waiver do not need to be reviewed and approved by M/OP/TC/COM prior to initiating procurement. However, records must be kept of all uses of the source/origin waiver authority. Decisions to use the source/origin waiver should be made in writing by the heads of operating units[2] or designees and should address the following issues:

1. The specific authority or authorities to be applied

2. The supplies or services to be acquired or the program being supported through an assistance award, with the estimated value of each award

3. The rationale supporting the decision, including the desired timing for the awards

4. For activities conducted outside of Africa (either in whole or in part)—

   - The decision memorandum should identify them as being carried out pursuant to HIV/AIDS and Infectious Disease Initiatives.

   - Direct Geographic Code 935 procurement should be authorized with provision in the award that procurement from the United States be maximized whenever practicable, consistent with program objectives.

Section E

How do these regulations and policies affect you as a procurer of pharmaceutical products?

The requirements for the procurement of pharmaceutical products using USAID funding are underpinned by statutory obligations and must be complied with. The "Buy America" policy does not preclude the procurement of non–U.S. source and/or origin products using USAID funds; however, the policy defines the criteria for doing so that must be complied with. Consequently, the implications of the USAID procurement regulations and policies for you, as a procurer of pharmaceutical products using USAID funding, are as follows:

- You should consider the probable source and origin of pharmaceutical products at the time of project or program development.

[2] *Operating unit* is the USAID field mission or USAID/Washington office or higher-level organizational unit that expends program funds to achieve a strategic objective, or special objective, and that has a clearly defined set of responsibilities focused on the development and execution of a strategic plan.

- You may need to allocate time and funding for preparing the request for approval to procure pharmaceutical products when planning your project or program, especially if the products are non-U.S. source and/or non-U.S. origin and/or non-FDA-approved.

- Obtaining approval to procure pharmaceutical products is only one step in the procurement process. You will need to consider the time needed to collate the required information for the request and also for the actual procurement process when preparing project or program work plans.

- You need to ensure that each request for approval is accompanied by all the data and information required to enable M/OP/TC/COM to make a decision. Submitting complete information will help avoid delays in the approval process and, consequently, in the implementation of your program.

Chapter 3

Obtaining USAID Approval to Procure Pharmaceutical Products: The Process

Chapter 3 describes the process to obtain USAID approval to procure pharmaceutical products. Section A describes the documents needed and a flowchart shows the USAID approval process. Individual roles and responsibilities are outlined in Section B. Section C contains a stepwise process for ensuring that you have considered all USAID requirements in preparing your request for approval to procure pharmaceutical products, and it includes a flowchart and checklists for information to be submitted with your application. Section C is cross-referenced with the relevant sections in Chapter 5, Sources of Information and Assistance. Finally, procedures for tracking your request and applying for amendments to previously approved requests are outlined in Sections D and E, respectively. Other USAID requirements for pharmaceutical procurement are described in Section F.

Section A

Overview of the process

1. What is the approval process?

The sequential list of steps to obtain approval to procure pharmaceutical products is as follows:

1. The USAID Mission or CA informs the CTO of the need to procure pharmaceutical products and the Mission/CA representative and CTO discuss the requirements to obtain approval.

2. The Mission/CA sends a letter to the CO or AO requesting permission to procure the pharmaceutical product. The request should include all of the information needed for the Management Bureau, Office of Procurement (M/OP) procurement official to make a decision. In particular, information should be included on the appropriateness of the product for the proposed application in the specific conditions in which it will be used, and for non–U.S. source and/or non–U.S. origin products, the justification for a source/origin waiver. For non-FDA-approved products apart from HIV test kits

listed in the source/origin waiver, sufficient data to attest to the safety, efficacy, and quality of the product should be included. The CTO is copied on this letter of request.

3. The CTO prepares the source/origin waiver, if needed. The source/origin waiver can be approved either by a USAID Bureau official or by a Mission official with appropriate authority. If the source/origin waiver is to be approved by a Mission official, the CTO submits the source/origin waiver for signature approval at this point.

4. The CTO then forwards his or her own technical recommendation for approval to the CO/AO, along with the source/origin waiver if needed.

5. If the product is not of U.S. origin or not FDA approved, the CO/AO forwards the request (including the signed source/origin waiver, if appropriate) to M/OP/TC/COM to seek concurrence for the approval. There is an exception for products listed in the HIV test kit source/origin waiver where approval for the procurement can be authorized by the relevant Bureau or Mission official with delegated authority without M/OP/TC/COM concurrence.

6. The M/OP/TC/COM procurement official reviews the technical information provided on the product and program and renders his or her decision to the CO/AO.

7. If the source/origin waiver is to be approved by a USAID Bureau official with the appropriate authority, the CO/AO forwards it at this point for signature approval.

8. The CO/AO reviews the entire request and sends the USAID Mission/CA a written response to its request to procure the commodity.

A flowchart showing the USAID approval process for procurement of U.S. source and origin, FDA-approved pharmaceutical products is shown in Figure 1. For non–U.S. source and/or U.S. origin and/or non-FDA-approved pharmaceutical products, see Figure 2.

Figure 1. USAID Approval Process for USAID-Funded Procurement of U.S. Source, U.S. Origin, FDA-Approved Pharmaceutical Products

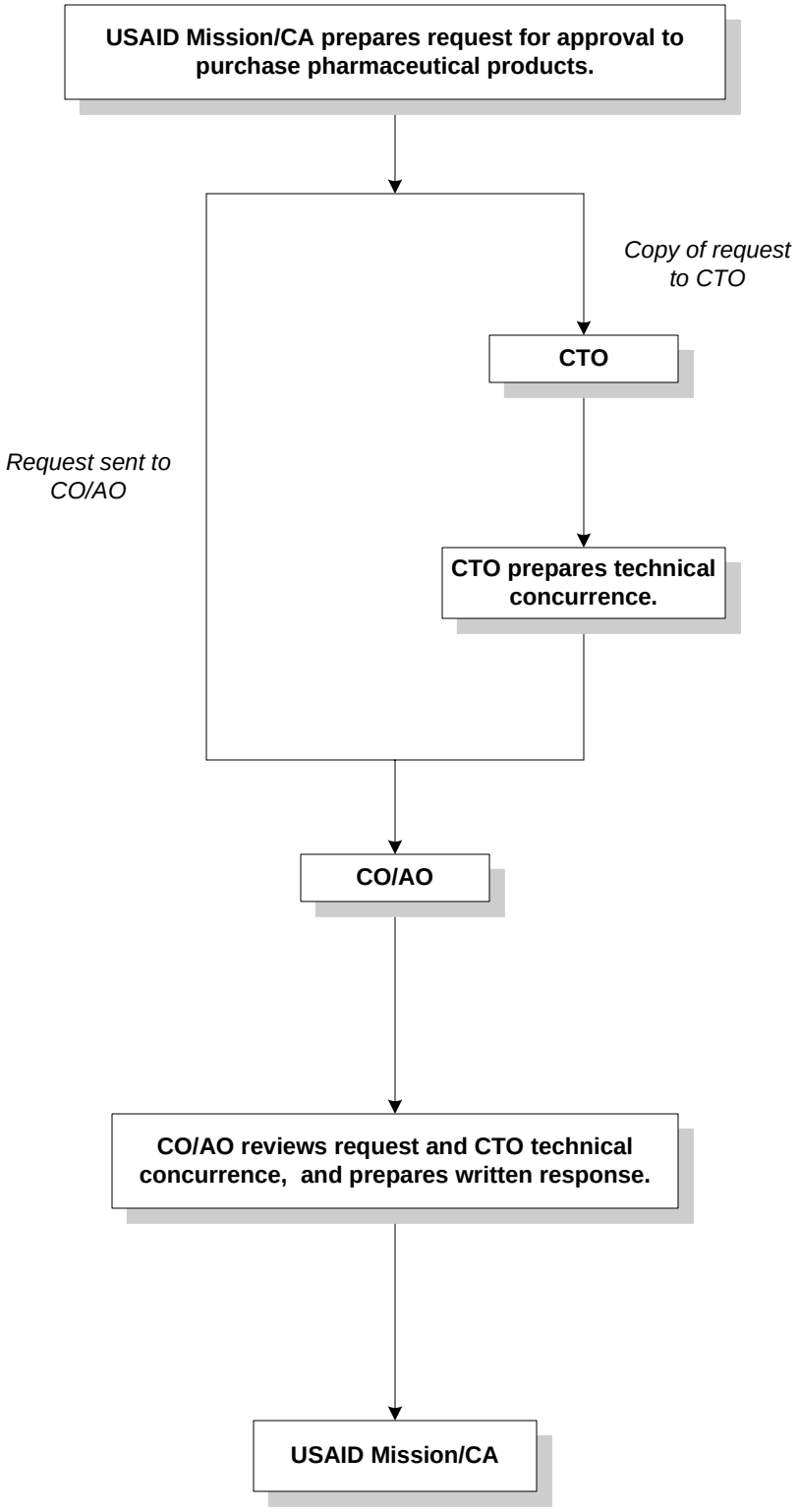
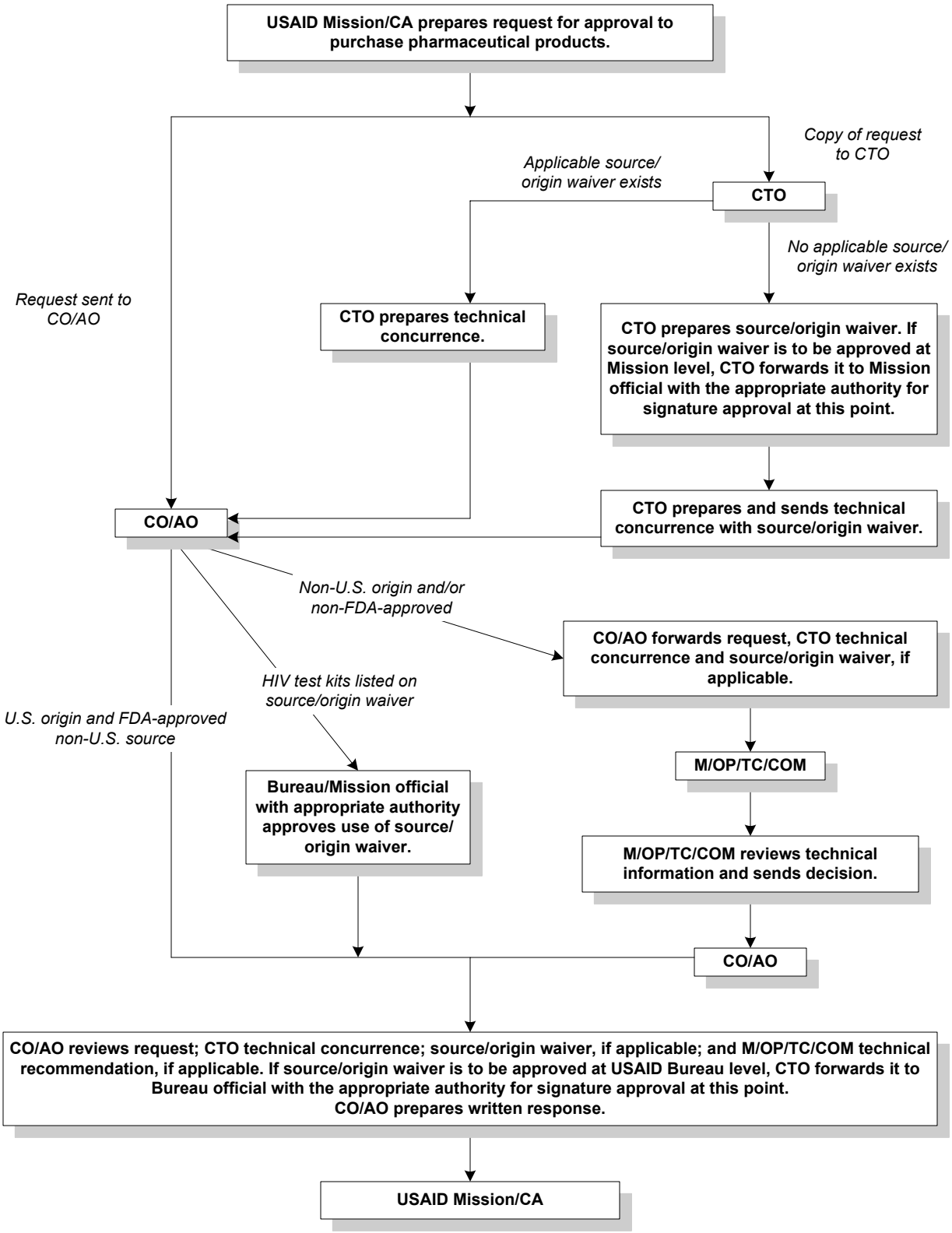


Figure 2. USAID Approval Process for USAID-Funded Procurement of Non–U.S. Source and/or Non–U.S. Origin, and/or Non-FDA-Approved Pharmaceutical Products



2. What documents and signatures are needed?

U.S. source and U.S. origin products

Approval for the USAID-funded procurement of U.S. source and U.S. origin pharmaceutical products requires the following documents and signatures:

- A request from the USAID Mission/CA to the CO/AO for approval to procure the product
- CTO technical concurrence
- For procurement of non-FDA-approved pharmaceutical products, M/OP/TC/COM technical concurrence
- Approval by the M/OP, namely the CO or AO

HIV test kits listed in source/origin waiver

Approval for the USAID-funded procurement of Geographic Code 935 source and/or origin HIV test kits, listed in Tab 1 of the source/origin waiver, requires the following documents and signatures:

- A request from the USAID Mission/CA to the CO/AO for approval to procure the product
- CTO technical concurrence
- Approval by the relevant Bureau or Mission official with delegated authority
- Approval by the M/OP, namely the CO or AO

Non–U.S. source and/or non–U.S. origin products other than HIV test kits listed in source/origin waiver

Approval for the USAID-funded procurement of non–U.S. source and/or non–U.S. origin pharmaceutical products requires the following documents and signatures:

- A request from the USAID Mission/CA to the CO/AO for approval to procure the product

- Source/origin waiver prepared by the CTO and approved by the relevant Bureau or Mission official with delegated authority, unless an applicable preapproved source/origin waiver exists
- CTO technical concurrence
- M/OP/TC/COM technical concurrence for non–U.S. origin and/or non-FDA-approved pharmaceutical products
- Approval by M/OP, namely the CO/AO

3. How long will it take to get a request approved?

It should take four to eight weeks to process a request for approval to procure a non–U.S. source/origin and/or non-FDA-approved pharmaceutical product from the date it is submitted to the date you receive a decision from your CO/AO. This estimate assumes your request for approval includes all the necessary information that M/OP requires to make a decision.

Section B

Roles and responsibilities

1. What is the USAID Mission/CA responsible for?

The Mission/CA is responsible for the following:

- Ensuring that the USAID Mission/CA officer who is responsible for procurement is fully informed on USAID procurement guidelines and on the specific contract/agreement/grant requirements and restrictions for pharmaceutical procurement. He/she may request advice and guidance from the CO/AO and CTO.
- Preparing the request for permission to procure pharmaceutical products, including—
  - Generic name, dosage form, strength or concentration, and unit pack size for drugs
  - Description and unit pack size for other products
  - Name of manufacturer and/or name of supplier, price per unit pack size, and total cost per product

- Intended therapeutic use for drugs and intended use for other products
- Information to attest that the product is appropriate for the proposed application in the specific context that it is to be used
- Information to attest to program capacity to use the product appropriately
- Rationale and justification for not procuring U.S. source and/or origin pharmaceutical products, if applicable
- Information to attest to safety, efficacy, and quality of non-FDA-approved products, if applicable

- Providing additional information to support the application as requested

2. What is the CO/AO responsible for?

The CO/AO is responsible for the following:

- Providing guidance and assistance to the USAID Mission/CA on administrative/contractual requirements and restrictions for pharmaceutical procurement under the contract/agreement/grant
- Forwarding the request for non–U.S. origin and/or non-FDA-approved pharmaceutical products, the CTO technical concurrence, and the source/origin waiver, if applicable, to M/OP/TC/COM
- Where the source/origin waiver is to be approved at Bureau level by USAID/Washington, forwarding the request to the USAID Bureau official with the appropriate authority for signature approval
- Reviewing the entire request and technical concurrences and responses and preparing a written response to the USAID Mission/CA

3. What is the CTO responsible for?

The CTO is responsible for the following:

- Providing guidance and assistance to the USAID Mission/CA on technical requirements and restrictions for pharmaceutical procurement under the contract/ agreement/grant
- Providing technical guidance to the USAID Mission/CA on preparing a request for approval
- Ensuring that the CO/AO receives the USAID Mission/ CA request for approval
- Providing or obtaining technical concurrence, which includes submitting comments on whether—
  - The request is within the terms of the agreement.
  - The product is appropriate for the proposed application in the specific context in which it is to be used.
  - The program has the capacity to ensure that the product is used appropriately.
  - Rationale and justification are provided for not procuring U.S. source and/or origin pharmaceutical products, if applicable.
  - Information is available to attest to safety, efficacy, and quality of non-FDA-approved products, if applicable.
- Preparing a source/origin waiver, if needed; where the source/origin waiver is to be approved at Mission level, forwarding the request to the Mission official with the appropriate authority for signature approval; and forwarding the source/origin waiver to the CO/AO
- Acting as a point of contact for the USAID Mission/CA and tracking the approval process

4. What is the USAID Bureau/Mission official responsible for?

The USAID Bureau/Mission official is responsible for the following:

- Reviewing and signing the source/origin waiver
- Approving the procurement of Geographic Code 935 source/origin HIV test kits listed in the HIV test kit source/origin waiver

5. What is M/OP/TC/COM responsible for?

M/OP/TC/COM is responsible for the following:

- Reviewing the request for approval to procure pharmaceutical products and providing technical control and oversight to ensure that—
  - The pharmaceutical product is appropriate for the proposed application in the specific context in which it is to be used.
  - The price and total cost of the pharmaceutical product are appropriate.
  - The program has the capacity to ensure that the product is used appropriately.
  - The rationale and justification for not procuring U.S. source and/or origin pharmaceutical products are appropriate and adequate, if applicable.
  - The product is either FDA approved or information is available to attest to safety, efficacy, and quality of the product.
- Rendering a decision to the CO/AO

Section C

Preparing for and writing the request for approval

1. What do you need to consider and what information do you need?

This section is written as a stepwise process to help you work through all the USAID requirements for pharmaceutical procurement using USAID funding. The steps are outlined in a flowchart in Figure 3. Each step is cross-referenced with the relevant section in Chapter 5, Sources of Information and Assistance. Refer to your CTO if any further clarification is needed.

Step 1

Does the contract/agreement/grant allow procurement of pharmaceutical products?

Not all USAID contracts/agreements permit procurement of pharmaceutical products.

- ***No.*** Consult your CO/AO about how to proceed.
- ***Yes.*** Go to Step 2.
- ***How to find out.*** Check the scope of work under the contract/agreement/grant or ask your CTO. If the contract/agreement/grant is not clear, ask for a ruling from your CO/AO.

Step 2

Select the pharmaceutical products that you need to procure for your project/program. Are the pharmaceutical products appropriate for the proposed application in the specific context in which they will be used?

USAID procurement regulations require that the pharmaceutical product be appropriate for the proposed application in the specific program context in which it will be used. For example, an HIV test kit that takes several days to produce a result is unsuitable for a program requiring same-day testing. Similarly, a product that requires refrigeration where no electricity or battery-operated refrigerators are available may be considered inappropriate for the program context.

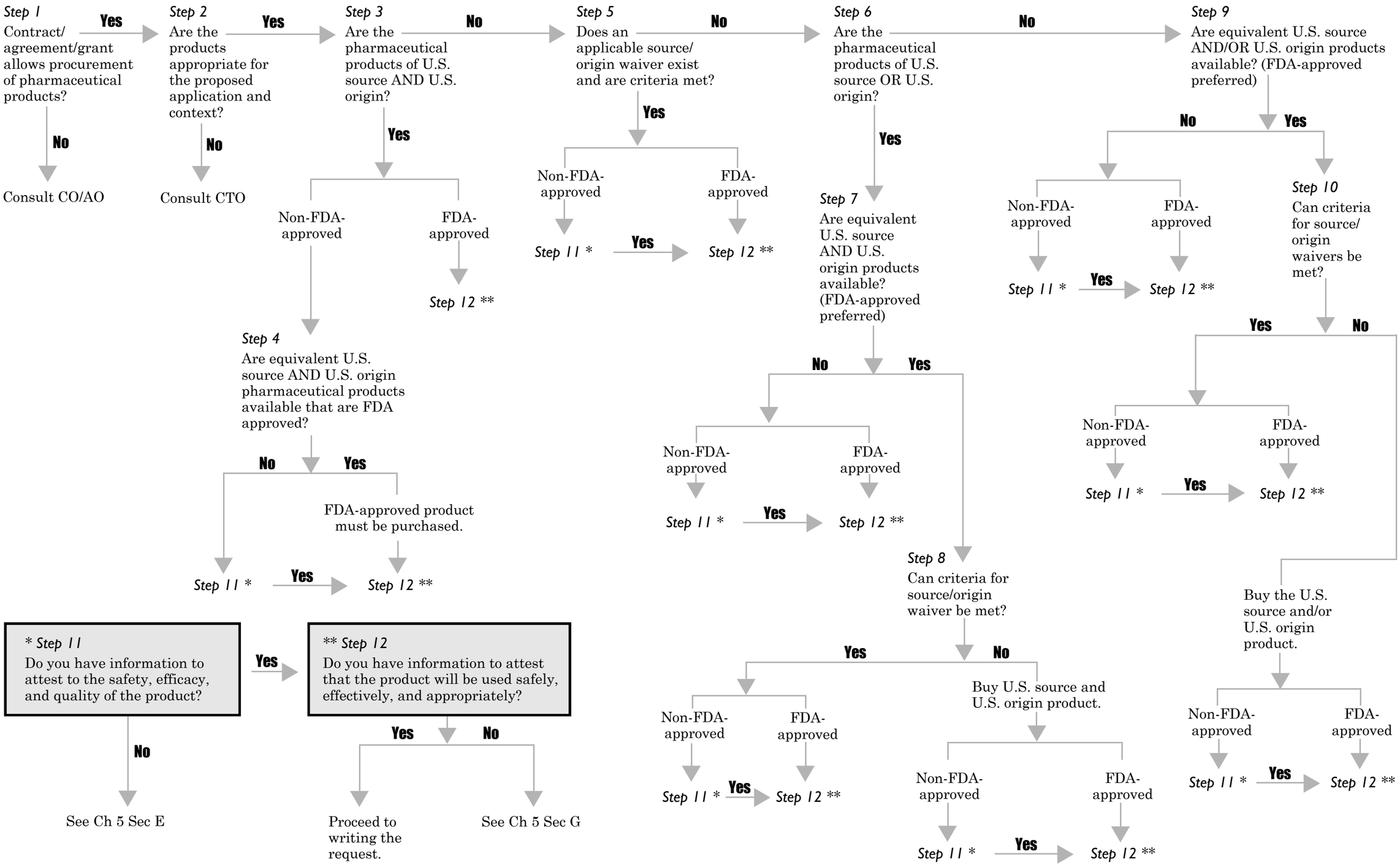
- ***No.*** Consult with your CTO about how to proceed. Your CTO may be able to advise you on the availability of a more suitable product.
- ***Yes.*** Go to Step 3.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section F, for more examples and consult your CTO.

Step 3

Are the pharmaceutical products of U.S. source AND of U.S. origin?

- ***No.*** Go to Step 5.
- ***Yes.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 4.
- ***How to find out.*** Check with the supplier or manufacturer. If you need to check the availability of products, see Chapter 5, Sources of Information and Assistance, Section B.

Figure 3. Steps in Addressing USAID Procurement Requirements



Step 4

Are pharmaceutical products, or ones that are substantially equivalent, available from a U.S. source AND of U.S. origin WITH FDA approval?

M/OP/TC/COM will expect you to consider FDA-approved products in preference to those that are not FDA approved and to justify why any available FDA-approved products are not "substantially equivalent." It is also preferable for you to procure FDA-approved products, if available; otherwise, you will need to submit information to attest to safety, efficacy, and quality of the non-FDA-approved product.

- ***No.*** Go to Step 11.
- ***Yes.*** The U.S. source and U.S. origin, FDA-approved products must be purchased. Go to Step 12.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section B.

Step 5

Does an applicable source/origin waiver under the contract/agreement/grant allow you to procure pharmaceutical products from USAID Geographic Code 935 sources, AND does the procurement meet the criteria of the source/origin waiver?

The contract/agreement/grant should reflect any source/origin waivers that are allowed under the Results Package. The source/origin waiver under the contract/agreement/grant may be restricted to certain categories of pharmaceutical products. For example, the source/origin waiver approved under HIV/AIDS Strategic Objective 4 Results Package applies only to selected pharmaceuticals for STDs and OIs. In addition, the source/origin waiver allows procurement from Geographic Code 935 **but only** if certain criteria, as described in the source/origin waiver itself, are met.

- ***No.*** Go to Step 6.
- ***Yes.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11. For HIV test kits, go to Step 12.
- ***How to find out.*** Check the contract/agreement/grant to see whether an approved source/origin waiver is available and what the criteria are for its use. The source/origin waiver for selected pharmaceuticals for STDs and OIs is included as Annex 5. The source/origin waiver for HIV/AIDS diagnostic materials (testing kits) is included as Annex 6. Also, you can ask your CTO to check that the source/origin geographic codes in the contract/agreement/grant correspond to the codes in the authorization document or Results Package.

Step 6

Are the pharmaceutical products of U.S. source OR of U.S. origin?

- ***No.*** Go to Step 9.
- ***Yes.*** Go to Step 7.
- ***How to find out.*** Check with the supplier or manufacturer.

Step 7

Are the pharmaceutical products, or ones that are substantially equivalent, available from a U.S. source AND of U.S. origin?

You **must** consider procurement from U.S. sources first. Products of U.S. origin **must** be considered before products of non-U.S. origin. In addition, M/OP/TC/COM will expect you to consider FDA-approved products in preference to those that are not FDA approved. It is also preferable for you to procure FDA-approved products, if available; otherwise, you will need to submit information to attest to safety, efficacy, and quality of the non-FDA-approved product.

- ***No.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***Yes.*** Go to Step 8.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section B.

Step 8

If U.S. source AND origin pharmaceutical products are available, can you still justify procurement of the non–U.S. source OR non–U.S. origin products under a source/origin waiver?

USAID regulations do permit exceptions to the U.S. source/origin rule even if an appropriate pharmaceutical product is available from a U.S. source, **but only if certain criteria are fulfilled.**

- ***No.*** The U.S. source and U.S. origin products must be purchased. For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***Yes.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section C.

Step 9

Are the pharmaceutical products, or ones that are substantially equivalent, available from a U.S. source AND/OR of U.S. origin?

You **must** consider procurement from U.S. sources first. Products of U.S. origin **must** be considered before products of non-U.S. origin. In addition, M/OP/TC/COM will expect you to consider FDA-approved products in preference to those that are not FDA approved. It is also preferable for you to procure FDA-approved products, if available; otherwise, you will need to submit information to attest to safety, efficacy, and quality of the non-FDA-approved product.

- ***No.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***Yes.*** Go to Step 10.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section B.

Step 10

If U.S. source AND/OR origin pharmaceutical products are available, can you still justify procurement of the non–U.S. source AND non–U.S. origin products under a source/origin waiver?

USAID regulations do permit exceptions to the U.S. source/origin rule even if an appropriate pharmaceutical product is available from a U.S. source, **but only if certain criteria are fulfilled.**

- ***No.*** The U.S. source and/or U.S. origin products must be purchased. For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***Yes.*** For FDA-approved products, go to Step 12. For non-FDA-approved products, go to Step 11.
- ***How to find out.*** See Chapter 5, Sources of Information and Assistance, Section C.

Step 11

Do you have information available to attest to the safety, efficacy, and quality of the non-FDA-approved product?

You will need to provide information to M/OP/TC/COM to attest that the pharmaceutical product is safe and efficacious for the proposed application and also that the quality of the product meets acceptable standards and has been manufactured in accordance with acceptable manufacturing practice requirements.

- ***No.*** See Chapter 5, Section E, on where to find the information.
- ***Yes.*** Go to Step 12.
- ***What do I need?*** Check Chapter 5, Sources of Information and Assistance, Section E.

Step 12

Do you have information available to attest that the product will be used safely, effectively, and appropriately in your program?

You need to satisfy M/OP that the product will be used safely, effectively, and appropriately in your program. You may also need to provide information on the design of the program itself and the capacity of the staff to use the product correctly.

- ***No.*** See Chapter 5, Sources of Information and Assistance, Section G, for where to get the information.
- ***Yes.*** Use the checklists in the next section to ensure that you have all the information that you need and then write the request.
- ***What do I need?*** Check Chapter 5, Sources of Information and Assistance, Section G.

2. Checklists of information to be included

This section provides five checklists for information that should be included in a request for approval to procure pharmaceutical products, according to the following categories:

Category A: U.S. source and origin products—Use checklists 1 and 2 to ensure that you have included all the necessary information in your request for approval.

Category B: Non–U.S. source and/or non–U.S. origin products and a preapproved, applicable source/origin waiver—Use checklists 1 and 3 to ensure that you have included all the necessary information in your request for approval. **HIV test kits covered by source/origin waiver**—Use checklist 4 only.

Category C: Non–U.S. source and/or non–U.S. origin products and no preapproved, applicable source/origin waiver—Use checklists 1 and 5 to ensure that you have included all the necessary information in your request for approval.

Checklist 1.

Information to be included in requests for all pharmaceutical products

Information to be included for all pharmaceutical products	For more information see Chapter 5, Sources of Information and Assistance:	✔
Contract/agreement/grant information: Project/project number/cooperating country Brief description of section(s) of approved scope of work relevant to procurement of pharmaceuticals		
Description of product: Drugs: generic name; dosage form; strength or concentration; unit pack size	Section A	
Diagnostic reagents/test kits: test name, description of the testing procedure used, and organism type/subtype detected; unit pack size; if applicable, complexity rating (centrifugation/additional equipment required and single-step/multistep assay); type of specimen used; time until result known; sensitivity/specificity	Section A	
Any special environmental requirements for storage or use	Section A	
Procurement information: Name and address of manufacturer, name and address of supplier (if different) Cost at point of purchase; delivered cost to clinic using a U.S. carrier unless inappropriate (includes storage and delivery charges, duty, taxes, and tariffs); total number of unit packs needed; total cost of procurement Statement that the supplier will be requested to comply with USAID special provisions on expiry dates for pharmaceutical products		
Proposed use: Intended use and information to attest that the pharmaceutical product is appropriate for the proposed application in the specific program/country context which it will be used	Section F	
Program information: Information to attest that product will be used safely, effectively, and appropriately in the program	Section G	

Checklist 2.

Additional information to be included in requests to procure U.S. source and U.S. origin products

Additional information	**For more information see Chapter 5, Sources of Information and Assistance:**	✔
Statement that the product is of U.S. source and origin		
FDA-approved products: Statement that the product is approved by the FDA for the proposed application		
Non-FDA-approved products: Information on the availability of the same product or a substantially equivalent product that is FDA approved and justification for not procuring this product, if applicable	Section B	
Information to attest to the safety, efficacy, and quality of the product	Section E	

Checklist 3.

Additional information to be included for a request to procure a non–U.S. source and/or origin product under a preapproved source/origin waiver (HIV test kits see Checklist 4)

Additional information for non–U.S. source and/or origin products under a preapproved source/origin waiver	**For more information see Chapter 5, Sources of Information and Assistance:**	✔
Source country (supplier) and origin country (manufacturer) of the product		
Source/origin waiver information: Details of approved source/origin waivers under your contract, categories of products to which the source/origin waiver applies, and geographic codes permitted as sources under the source/origin waiver Statement that the product belongs to an approved category of products as specified in the source/origin waiver Statement that procurement is from a permitted source as specified in the source/origin waiver		
Information to attest that the criteria under the preapproved source/origin waiver are fulfilled: Justification that the product is essential for the activity Information to attest that the product in the same or substantially equivalent form is not available from the United States or that the delivered price would be at least 50% more than from a non-U.S. source or origin The product meets the standard of the U.S. FDA or other controlling U.S. authority or information to attest to safety, efficacy, and quality of product (see below) Information on promoting efficient use of foreign assistance resources, if applicable	Section C1 Section C2 or Section C3 Section C4 or Section C5 Section C7	
FDA-approved products: Statement that product is FDA approved for the proposed application		
Non-FDA-approved products: Information on the availability of the same product or a substantially equivalent product that is FDA approved and justification for not procuring that product, if applicable Information to attest to the safety, efficacy, and quality of the product	Section B Section E	
U.S. patent information: Statement that the planned procurement does not violate any U.S. patents or that express authorization of the patent holder has been given Statement that manufacturers/suppliers will be required to certify on their invoices that the items supplied do not infringe any U.S. patents	Section C6	

Checklist 4.

Information to be included in requests for Geographic Code 935–source HIV test kits, listed in source/origin waiver

Information to be included for Geographic Code 935–source HIV test kits, listed in source/origin waiver	**For more information see Chapter 5, Sources of Information and Assistance:**	✔
Contract/agreement/grant information: Project/project number/cooperating country Brief description of section(s) of approved scope of work relevant to procurement HIV test kits		
Description of product: Test name, unit pack size Additional information as requested (may include description of the testing procedure used and HIV type/subtype detected; complexity rating [centrifugation/additional equipment required and single-step/multistep assay]; type of specimen used; time until result known; sensitivity/specificity) Any special environmental requirements for storage or use	Section A Section A Section A	
Procurement information: Name and address of manufacturer, name and address of supplier (if different) Cost at point of purchase; delivered cost to clinic using a U.S. carrier unless inappropriate (includes storage and delivery charges, duty, taxes, and tariffs); total number of unit packs needed; total cost of procurement Statement that the supplier will be requested to comply with USAID special provisions on expiry dates for pharmaceutical products		
Proposed use: Intended use and information to attest that the pharmaceutical product is appropriate for the proposed application in the specific program/country context in which it will be used	Section F	

Checklist 4 continued on next page

Checklist 4.

Information to be included in requests for Geographic Code 935–source HIV test kits, listed in source/origin waiver (continued)

Information to be included for Geographic Code 935–source HIV test kits, listed in source/origin waiver	**For more information see Chapter 5, Sources of Information and Assistance:**	✔
Program information: Information to attest that product will be used safely, effectively, and appropriately in the program	Section G	
Source country (supplier) and origin country (manufacturer) of the product		
Source/origin waiver information: Details of approved source/origin waivers under your contract, categories of products to which the source/origin waiver applies, and geographic codes permitted as sources under the source/origin waiver Statement that the HIV test kit is included in the approved list of products as specified in the source/origin waiver Statement that procurement is from a permitted source as specified in the source/origin waiver		
FDA-approved products: Statement that product is FDA approved for the proposed application		
Non-FDA-approved products: Statement that, as stated in the waiver, the U.S. Centers for Disease Control and Prevention (CDC) has reviewed and approved the test kit for safety and efficacy		

Checklist 5.

Additional information to be included for a request to procure a non–U.S. source and/or origin product when no preapproved source/origin waiver exists or applies

Additional information to be included for non–U.S. source and/or origin product when no preapproved source/origin waiver exists or applies	**For more information see Chapter 5, Sources of Information and Assistance:**	✔
Source country (supplier) and origin country (manufacturer) of the product		
Information to attest that the criteria for approval of a source/origin waiver are fulfilled: Justification that the product is essential for the activity	Section C1	
Information to attest that the product in the same or substantially equivalent form is not available from the United States or that the delivered price would be at least 50% more than from a non-U.S. source or origin	Section C2 or Section C3	
The product meets the standard of the U.S. FDA or other controlling U.S. authority or information to attest to safety, efficacy, and quality of product (see below)	Section C4 or Section C5	
Information on promoting efficient use of foreign assistance resources (if applicable)	Section C7	
FDA-approved products: Statement that product is FDA approved for the proposed application		
Non-FDA-approved products: Information on the availability of the same product or a substantially equivalent product that is FDA approved and justification for not procuring that product, if applicable	Section B	
Information to attest to the safety, efficacy, and quality of the product	Section E	
U.S. patent information: Statement that the planned procurement does not violate any U.S. patents or that express authorization of the patent holder has been given		
Statement that manufacturers/suppliers will be required to certify on their invoices that the items supplied do not infringe any U.S. patents	Section C6	

3. Writing the request for approval

You should now have all the information you need to write the request for approval to procure pharmaceutical products. The sample applications in Annexes 8 and 9 can be used as a framework. Your request for approval should be submitted to your CO/AO and a copy sent to your CTO. Your CO/AO will reply to your request. It should take from four to eight weeks to process a request for approval to procure non–U.S. source/ origin and/or non-FDA-approved pharmaceutical products from the date of submission to the date of receipt of a decision from your CO/AO. This estimate assumes your request for approval includes all the necessary information that M/OP requires to make a decision.

Section D

Tracking your application

Contact your CTO to obtain information on the current status of your request in the approval process. All queries should always be addressed through the CTO. As mentioned previously, processing should take from four to eight weeks. This estimate assumes your request for approval includes all the necessary information that M/OP requires to make a decision.

Section E

Applying for amendments to previously approved requests

If at all possible, try to avoid the need to apply for amendments to previously approved requests for pharmaceutical procurement. A request for an amendment may not necessarily be easier or require less time to process than the original request.

An application for an amendment to a previously approved request will need to include the following information:

- An explanation as to which product it is replacing and why. If the amendment is for an additional product, state why it is needed.
- An explanation as to why this product was not requested in the original application.
- Information detailed in the checklists in Chapter 3, Section C2, as appropriate.

Section F

Other USAID requirements relevant to pharmaceutical procurement

You may need to comply with other USAID requirements relevant to the procurement of pharmaceutical products under your contract/agreement/grant.

1. Competitive procurement

For orders in excess of $25,000, USAID regulations on competitive procurement require that the USAID Mission/CA notify the Office of Small Disadvantaged Business Utilization, USAID, and, in addition, advertise the procurement in *Commerce Business Daily* and the *USAID Procurement Information Bulletin* before it buys the pharmaceuticals. However, a December 19, 2000, Action Memorandum, Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives, approved certain waivers to full and open competitive procurement and expedited procedures to acquire commodities for USAID's HIV/AIDS and Infectious Diseases Initiatives. This memorandum is attached as Annex 7 and is also available at **http://www.usaid.gov/pubs/ads/300/updates/iu3-0101.doc** [accessed December 20, 2001].

Refer to the contract/agreement/grant and check with your CO/AO for further guidance.

2. Transportation of commodities

Generally, USAID-funded procurements must be transported on U.S. ocean/air flag carriers. Quotes for delivered price of pharmaceutical products must take this requirement into account unless the contract/agreement/grant clearly states otherwise.

Refer to the contract/agreement/grant and check with your CO/AO for further guidance.

3. Marking of USAID-financed commodities

USAID regulations require that USAID-financed commodities be marked to identify them as being provided under a U.S. foreign assistance program.

Refer to the contract/agreement/grant and check with your CO/AO for further guidance.

Part II

Sources of Information and Assistance

Chapter 4

Frequently Asked Questions

What are simple/rapid HIV test kits and why use them?

HIV testing can be used for the diagnosis of HIV infection, for surveillance, and for the screening of blood. The testing strategy and selection of kits depend on the objective of the test and the context in which it is to be used. Currently, the U.S. diagnostic technique uses tests based on the ELISA (enzyme-linked immunoassay) to screen a specimen; if the result is positive, it is confirmed using a Western blot test.[3] However, ELISA and Western blot tests are expensive and require high-quality laboratory facilities and highly trained personnel that are not readily available in developing countries. In addition, experience has shown that given the time required to transport specimens to the laboratory, perform the test in batches, and transmit the test results, tested persons typically must wait one to two weeks before they return to get their results.[4]

Advances in technology have led to the development of a number of simple/rapid HIV tests. Most simple/rapid tests are presented in a kit form that requires no other reagent or equipment, involves a limited number of steps, and generally includes an internal quality control. Many simple/rapid tests do not require electricity, highly trained staff, or refrigeration. A preliminary result is available in less than 45 minutes and is easy to interpret.[5] Studies have demonstrated that testing algorithms or combinations of these tests can produce reliable results, comparable to those of the standard ELISA and Western blot.[6] The availability of simple/rapid assays for voluntary HIV counseling and testing has a particular advantage in offering same-day results, thus substantially reducing the proportion of clients tested who do not return to learn their results.

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[3] CDC (December 2000), "HIV Testing Technologies for Use in HIV Serosurveillance in Developing Countries: Selection, Evaluation, and Implementation" (draft).

[4] Bernard M. Branson (2000), Rapid Tests for HIV Antibody, *AIDS Rev.* 2: 76–83.

[5] See note 3.

[6] See note 4.

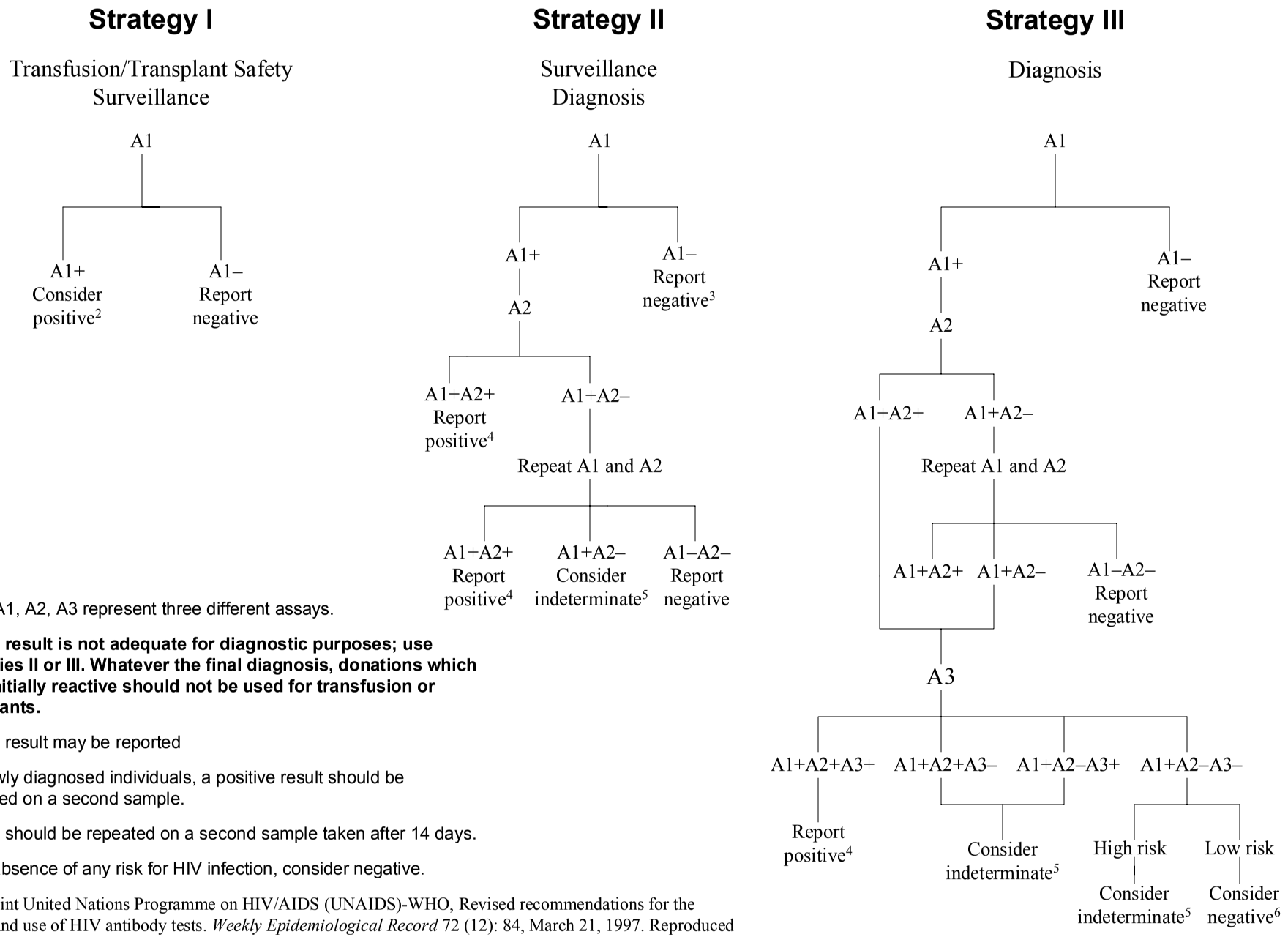
Why is it necessary to buy more than one simple/rapid HIV test kit?

The joint United Nations Programme on HIV/AIDS [UNAIDS] and the World Health Organization (WHO) recommend the use of three testing strategies to maximize accuracy while minimizing cost. The choice of the most effective strategy depends on the objectives of the test and the prevalence of HIV in the sample population (Figure 4).[7] The probability that a test will accurately determine the true infection status of a person being tested varies according to the background prevalence of HIV. In general, the higher the prevalence of HIV in a population, the greater the probability that a person testing positive is positive and, conversely, the higher the proportion of false negatives. Therefore, the strategies to diagnose HIV infection require the use of at least two and usually three antibody assays all of which should use different antigens and/or different formats and are required to be used in a specified order. The order of use is determined by the specificity and sensitivity of the tests, with the first test having a higher sensitivity (> 99% with specificity > 95%) and therefore detecting fewer false negatives, and the second and third having a higher specificity (> 99% with sensitivity > 95%) and therefore fewer false positives.

Many cooperating countries have subsequently adopted or are in the process of formulating guidelines that require the use of two or three simple/rapid HIV test kits for counseling and voluntary HIV testing. Consequently, if you are procuring simple/rapid HIV test kits for a voluntary counseling and testing (VCT) program, you will need to procure at least two, and perhaps three, simple/rapid HIV test kits. Contact the cooperating country or, alternatively, the U.S. Centers for Disease Control and Prevention (CDC) to obtain information on the HIV testing algorithm that has been designed and evaluated for the region in which you plan to establish the program.

[7] UNAIDS/WHO (1997), Revised Recommendations for the Selection and Use of HIV Antibody Tests, *Weekly Epidemiological Record* 72, 12: 81–87.

Figure 4: Schematic Representation of the UNAIDS and WHO HIV Testing Strategies [1]



[1] Assay A1, A2, A3 represent three different assays.

[2] **Such a result is not adequate for diagnostic purposes; use strategies II or III. Whatever the final diagnosis, donations which were initially reactive should not be used for transfusion or transplants.**

[3] Report: result may be reported

[4] For newly diagnosed individuals, a positive result should be confirmed on a second sample.

[5] Testing should be repeated on a second sample taken after 14 days.

[6] In the absence of any risk for HIV infection, consider negative.

Source: Joint United Nations Programme on HIV/AIDS (UNAIDS)-WHO, Revised recommendations for the selection and use of HIV antibody tests. *Weekly Epidemiological Record* 72 (12): 84, March 21, 1997. Reproduced by the kind permission of UNAIDS and the World Health Organization.

Why is only one FDA-approved rapid HIV test kit available?

Until 1998, CDC recommended withholding the results of an initially positive HIV test result until a confirmatory report had been received so there was little market demand for FDA-approved rapid HIV test kits. However, in 1998 CDC revised its recommendations and encouraged wider use of rapid HIV testing in view of data that supported the idea that the opportunity to counsel and care for a patient with HIV infection outweighed the concern of reporting initially positive results that might later prove to be negative. Although ideal rapid-testing technologies are not yet available in the United States, the change in the CDC's recommendations gave manufacturers an economic incentive to seek FDA approval.

Why does it take so long to get a source/origin waiver approved?

If the USAID Mission or CA and the CTO understand the process and provide the information needed, experience shows that approval to procure pharmaceutical products can be obtained in a four- to eight-week period. This estimate assumes the request for approval includes all the necessary information that M/OP requires to make a decision. One of the most frequent reasons cited by M/OP/TC/COM for the delays in processing requests for approval was the omission or incompleteness of supporting documentation.

How long might it take me to collect all the relevant information on a non–U.S. source/origin, non-FDA-approved pharmaceutical product for submission in support of a source/origin waiver application?

To some extent, the time needed to collect all the relevant information will depend on the level of cooperation you receive. The evidence to substantiate that the product is essential to the activity should be readily available. For non–U.S. source/origin products, checking if the same or an equivalent product is available from the United States can take time. Contacting a U.S. wholesaler can often be the fastest and easiest method to obtain this information. U.S.

price comparison documentation can be obtained readily from published sources such as the *Drug Topics® Red Book®*.[8] Similarly, U.S. patent information for drugs can rapidly be retrieved from the FDA Web site.

For non-FDA-approved pharmaceutical products, manufacturers and distributors with rigorous internal quality control programs, who are familiar with international procurement requirements, will have most of the supporting quality documentation available. They should be able to provide the information that you need to submit with your application to attest to the quality of the product in a matter of weeks. Much of the documentation to attest to the safety and efficacy of the pharmaceutical product for the proposed application should be available from the background research that was used to develop the proposal for the program. Obtaining information for newer products, or for newer therapeutic uses or other than standard dosage regimens, may take additional time. Again, information on the monitoring procedures that will be incorporated into the program to reflect the contraindications and side-effect profile of the pharmaceutical products should have been developed as part of the program design.

Why does it take so long to get products into country and into the activity after the source/origin waiver is approved?

Obtaining approval to procure pharmaceutical products is only one step in the procurement process. USAID Missions and CAs still need to comply with USAID regulations on competition and procurement. In addition, the actual procurement, importation into country, and distribution to the program sites can all affect the procurement/delivery time.

[8] The *Drug Topics® Red Book®* is an annual publication that contains a listing of U.S. drugs, manufacturers' names, average U.S. wholesale prices and direct prices, and manufacturer and wholesaler information. The publication is available from Spectrum (Telephone 1-800-678-5689 or E-mail **sales@spectrumchemical.com**).

Do I need to resubmit the source/origin waiver application, once granted, if the project expands or needs a subsequent supply? (Does the granted waiver apply to a single procurement or to a project?)

Generally, source/origin waivers are approved for single procurements or for procurements that will take place over a short period of time because the circumstances under which a source/origin waiver was approved may change over time; for example, an equivalent product may be approved by FDA.

Do I send in the originals of certificates, signed affidavits, etc., with my request for approval to procure pharmaceutical products?

No, generally copies will do. It is possible to obtain approval without copies, but copies help support the application.

Does an "appeal" process exist?

Although no official "appeal" process exists, it is possible to move up the chain of command from M/OP/TC/COM.

Chapter 5

Sources of Information and Assistance

This section is intended to assist USAID Missions and CAs in preparing requests for approval to procure pharmaceutical products as outlined in Chapter 3. It is not intended to be read from cover to cover. Refer to a specific section when necessary. Details and examples of the information to be provided are described and sources that can be used to obtain this information are suggested. An outline of the contents of this chapter follows.

Section A

Description of pharmaceutical products

Section A outlines information that should be included in the description of pharmaceutical products and suggests possible sources where the information can be obtained.

Contents of Section A

2. *Description of drugs*

   - *Information to be included*
   - *Sources of information*
   - *Examples*

3. *Description of pharmaceutical products other than drugs and HIV test kits*

   - *Information to be included*
   - *Sources of information*
   - *Example*

1. Description of HIV test kits

Information to be included

The information in **boldface** type should be sufficient for requests for approval to procure—

- U.S. source and origin, FDA-approved HIV test kits
- Non–U.S. source and/or origin HIV test kits listed on Tab 1 of the HIV test kit source/origin waiver

For non-FDA-approved and/or non–U.S. source and/or origin test kits not listed in Tab 1 of the HIV test kit source/origin waiver, include all the information, particularly if you are requesting approval to procure any of these HIV test kits in preference to an FDA-approved product and/or a product of U.S. source and/or U.S. origin.

a. Test name

b. Brief description of testing procedure used

c. HIV type/group detected

d. Complexity rating

   Use either the CDC complexity rating system for HIV test kits or describe the additional equipment requirements including centrifugation, whether it is a single-step or multistep assay, and ease of interpretation of result.

e. Type of specimen used, for example, whole blood, plasma, or saliva

f. Time until results known

g. Sensitivity and specificity of assay

h. Unit pack size

i. Special storage conditions

Sources of information

- Manufacturer/supplier

  Contact information for manufacturers of selected HIV test kits is included in Annex 11.

- Package insert

  Check with manufacturer to ensure you have the latest version of the package insert.

- Manufacturer/supplier Web site

  Information on Web sites may be outdated, and you may need to verify with the manufacturer/supplier that the information is still current. Web site addresses for manufacturers of selected HIV test kits are included in Annex 11.

- "Rapid Tests for HIV Antibody," a paper prepared by Dr. Bernard M. Branson from CDC, summarizes data on the characteristics and performance of rapid HIV tests from peer-reviewed journals and conference abstracts. Data from test manufacturers are not included unless corroborated by independent evaluations. This article is available from *AIDS Reviews 2000*, 2: 76–83, and is currently also available at **http://www.medadvocates.org/cdc/rapidtest.html** [accessed December 20, 2001].

- CDC

  CDC provides consultation and assistance to developing countries to evaluate HIV test kits to determine an appropriate HIV testing methodology and algorithm to be used in a particular health care setting. CDC can assist USAID Missions/CAs in kit selection and with

information for preparing requests for approval to procure HIV test kits. Contact information for CDC is listed in Annex 12.

- WHO

  WHO periodically evaluates ELISAs and simple/rapid HIV test kits that are available for bulk purchase by the public sector. Results of these evaluations are available on the WHO Web site in Comparative Evaluation of the Operational Characteristics of Commercially Available Assays to Detect Antibodies to HIV-1 and/or HIV-2 in Human Sera, available from **http://www.who.int/pht/blood_safety/hivkits.html** [accessed December 20, 2001].

Example of Description Information for a Rapid HIV Test Kit

Name of test:	Determine™ HIV-1/2
Test method:	Lateral flow[1] Immunochromatographic qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2[2]
HIV type/subtype detected:	HIV-1, HIV-2 [2]
Complexity rating:	CDC complexity rating 1: Sample manipulation limited to application followed by addition of buffer reagent or wash. Easily read. No additional equipment or centrifugation needed.[1]
Type of specimen used:	Serum, plasma, or whole blood by venipuncture or whole blood by fingerstick. Whole blood collected by fingerstick must be tested immediately.[2]
Time until results known:	Minimum of 15 minutes and up to 60 minutes[2]
Sensitivity and specificity:	Sensitivity: 97.9–100%; Specificity: 100%[1]
Unit pack size:	10 tests per card; 10 tests per pack[2]
Special storage conditions:	Test kits stored at 2–30 degrees C[2]

[1] B.M. Branson, Rapid Tests for HIV Antibody, *AIDS Reviews 2000,* 2: 76–83.
[2] Determine™ HIV-1/2 package insert (January 1998).

2. Description of drugs

Information to be included

a. Generic name

b. Dosage form; include route of administration where several alternative forms exist

   For example, with nystatin tablets, specify if vaginal tablets or oral tablets are to be procured.

c. Strength or concentration; for injections include the vial/ampoule size

d. Unit pack size

e. Special storage conditions such as, for example, refrigeration

Sources of information

- Wholesaler catalogue/listing

  May not contain information on special storage conditions

- *Drug Topics® Red Book®*[9]

  Does not contain information on special storage conditions

- Wholesaler/manufacturer

Examples of Description Information for Drugs

Azithromycin tablets 250mg – 4 tablets per pack

Gentamycin injection 40mg/ml 2ml unit dose vial – 100 vials per pack

Nystatin vaginal tablets 100,000 units – 15 per pack

Penicillin G benzathine injection 2.4 MU powder multidose vial – 100 vials per pack (store at 2–8 degrees C)

[9] See note 8.

3. Description of pharmaceutical products other than drugs and HIV test kits

Information to be included

For diagnostic reagents and test kits, include the information described for HIV test kits in Section A1. For other pharmaceutical products, include—

a. Product name

b. Indication

c. Unit pack size

d. Special storage conditions, for example, refrigeration

Sources of information

- Manufacturer/supplier
- Package insert

  Check with manufacturer to ensure you have the latest version.

- Manufacturer/supplier Web site

  Information on Web sites may be outdated, and you may need to verify with the manufacturer/supplier that the information is still current.

- Manufacturer/supplier catalogue/listing

Example of Description Information for Pharmaceutical Products Other than Drugs, Diagnostic Reagents, and Test Kits

Product name:	Benzylpenicillin E-test strips
Indication:	Antimicrobial susceptibility testing for *Neisseria Gonorrhoeae*
Unit pack size:	50

Section B

Checking the availability of pharmaceutical products

The procedures described in this section can be used to check the availability of a pharmaceutical product simply to locate a supplier for that product. However, this section can also be used to check the availability of a U.S. source and/or U.S. origin product and/or one that is substantially equivalent to comply with USAID requirements to procure products under a source/origin waiver (see Section C).

Contents of Section B

1. HIV test kits, checking availability from U.S. sources

Three methods of checking the availability of **FDA-approved HIV test kits** from U.S. sources are described, namely, contacting CDC, using the FDA Web site, and contacting U.S. wholesalers. Instructions on how to use each source are given and an example is provided where appropriate.

Many **non-FDA-approved HIV test kits** are manufactured in the United States and/or are available from U.S. sources, and a significant number of these products have been tested by the FDA and found to be unsatisfactory with regard to efficacy and quality. Non-FDA-approved HIV test kits from U.S. sources should only be purchased if information is available to attest to the safety, efficacy, and quality of the product. For example, if the HIV test kits have been tested, evaluated, and recommended by CDC and/or WHO for inclusion in a country's testing algorithm. See Section E1 for more information on USAID requirements for attesting to the

safety, efficacy, and quality of non-FDA-approved HIV test kits. Two of the methods described below can be used to check the availability of non-FDA-approved HIV test kits from U.S. sources: contacting CDC and contacting U.S. wholesalers. The FDA Web site can be used to obtain information only on FDA-approved test kits.

Contacting CDC

CDC consults with developing countries and provides assistance to evaluate HIV test kits to determine an appropriate HIV testing methodology and algorithm to be used in a particular health care setting. CDC can assist USAID Missions/CAs in preparing requests for approval to procure HIV test kits by providing information on availability from U.S. sources. Contact information for CDC is listed in Annex 12.

Using the FDA Web site

The FDA Web site offers the easiest and most up-to-date method to obtain information on the availability of FDA-approved HIV test kits and is easily accessible if Internet access is available. This method can also be used to check the availability of FDA-approved human T-lymphotropic virus (HTLV) and hepatitis test kits.

The main disadvantage of using the FDA Web site is that the pharmaceutical company that originally applied for FDA approval for each product is listed but not the current manufacturer. You need to contact the applicant to find the current manufacturer and, in turn, the origin of the product. In addition, contact information for the applicant is not given.

How to use the FDA Web site

The following Web-site addresses were current as of December 20, 2001. Addresses to Web-site pages can change as sites are updated. If the site is listed as unavailable, begin your search from the FDA home page **www.fda.gov/**. Under "Products FDA Regulates" click on "Biologics," then click on "Products." To find a list of Licensed/Approved HIV, HTLV, and Hepatitis Tests, under "Products," click on "HIV/Hepatitis Tests."

- Search Licensed/Approved HIV, HTLV, and Hepatitis Tests at **www.fda.gov/cber/products/testkits.htm** for manufacturers of HIV/HTLV/hepatitis test kits [accessed

December 20, 2001]. This document is current and is updated when an HIV, HTLV, or hepatitis test kit is approved.

- Contact the applicant manufacturer listed to request information on the current manufacturer and availability. Contact information for manufacturers of selected HIV test kits is listed in Annex 11.

Example: Checking the Availability of FDA-Approved Rapid HIV Test Kits from U.S. Sources

Searching www.fda.gov/cber/products/testkits.htm for rapid HIV test kits gives the information that on December 20, 2001, only one FDA-approved rapid HIV test kit is available, "Murex SUDS HIV-1 Test." The applicant manufacturer is listed as Murex Diagnostics, Inc.

Checking the information for rapid HIV test kits in Annex 11 lists the manufacturer of SUDS HIV-1 as being Abbott Diagnostics Division, telephone 1-800-323-9100.

Contacting Abbott Diagnostics Division gives the information that SUDS HIV-1 is manufactured in the United States and therefore is of U.S. origin.

Contacting U.S. wholesalers

If you need to check the availability of several HIV test kits, contacting two or three U.S. wholesalers may be the easiest method. A list of U.S. wholesalers is not currently available on the Internet. However, the *Drug Topics*® *Red Book*®[10] contains a Pharmaceutical Wholesaler Directory, and a copy from the 2001 edition is included in Annex 13.

2. HIV test kits, checking availability from non-U.S. sources

The availability of HIV test kits from non-U.S. sources can be checked by contacting CDC, international pharmaceutical suppliers/agencies, manufacturers, and local suppliers. This section is not intended to be comprehensive, and supplier information is used for illustration and does not imply that these suppliers are endorsed or preferred over others by USAID or RPM Plus.

[10] See note 8.

Contacting CDC

CDC consults with developing countries and provides assistance to evaluate HIV test kits to determine an appropriate HIV testing methodology and algorithm to be used in a particular health care setting. CDC can assist USAID Missions/CAs in preparing requests for approval to procure HIV test kits by providing information on their availability from non-U.S. sources. Contact information for CDC is listed in Annex 12.

Contacting international pharmaceutical suppliers/agencies

International pharmaceutical suppliers/agencies can be contacted directly to obtain information on the availability of HIV test kits from non-U.S. sources. One source of contact information for international suppliers is the Management Sciences for Health (MSH) *International Drug Price Indicator Guide*. The contact information for the international suppliers/agencies from the *International Drug Price Indicator Guide* is in Annex 10.

Contacting the manufacturer

The manufacturer of the HIV test kit can be contacted directly to request information on the availability of the product from non-U.S. sources including, for example, the country of origin if manufactured outside of the United States, or from suppliers in the cooperating country itself.

The Web sites of manufacturers frequently give contact information for company offices in different regions of the world that can be contacted directly to obtain information on the availability of their product from sources outside of the United States. Contact information for manufacturers of selected HIV test kits is given in Annex 11.

Contacting local wholesalers/suppliers in the cooperating country

The ministry of health, the USAID field office, the national AIDS committee, or the national regulatory authority in the cooperating country can be contacted with a request for a list of reliable and reputable wholesalers/suppliers that are known to supply HIV test kits of acceptable safety, efficacy, and quality. See Section E3 on USAID requirements to assure quality, safety, and efficacy of non-FDA-approved HIV test

kits. The wholesaler/supplier can then be contacted directly to request information on the availability of the HIV test kit.

3. Drugs, checking availability from U.S. sources

Three methods can be used to check the availability of **FDA-approved drugs** from U.S. sources, namely, contacting U.S. wholesalers, using the *Drug Topics® Red Book®*[11], and using the FDA Web site. Instructions on how to use each source are outlined and an example is given where appropriate.

Non-FDA-approved drugs are rarely available from U.S. sources and therefore are not considered.

Contacting U.S. wholesalers

Contacting U.S. wholesalers is the easiest method to check the availability of drugs from U.S. sources, particularly if you have many drugs to procure or if the product is available from many U.S. manufacturers. A list of U.S. wholesalers is not currently available on the Internet. However the *Drug Topics® Red Book®* contains a Pharmaceutical Wholesaler Directory that includes contact information. A copy of the directory from the 2001 edition is included as Annex 13.

Contact two or three wholesalers and request information on the availability of each product from U.S. sources. Specify that the products should be produced in the United States (that is, of U.S. origin) unless none are available.

The *Drug Topics® Red Book®*

The *Drug Topics® Red Book®* is an annual publication that contains a listing of U.S. drugs, manufacturers' names, average U.S. wholesale prices and direct prices as well as manufacturer and wholesaler information. The disadvantage of using the *Drug Topics® Red Book®* is that the country of origin of the product is not listed. If you are procuring many products, you may find it easier to approach U.S. wholesalers (see previous section) and ask them to get the information for you.

[11] See note 8.

- Go to the "Rx Products" listing if the product is a prescription-only drug in the United States or to the "OTC [over-the-counter]/Non-Drug Products" listing for other drugs. Check both sections if you are not sure which category the product belongs to.

- Check the manufacturer listing under both the generic name and each brand name for the product (dosage form/ route/strength) to get a complete list of products that are available from U.S. sources. Brand-name products are cross-referenced by manufacturer under the generic name in "Rx Products" but not in "OTC/Non-Drug Products."

- Combination products are listed alphabetically by ingredients using standard abbreviations that are listed at the beginning of both sections. However, it is easier to look up a well-known brand name for the product first to correctly identify the generic name that is used in the *Drug Topics® Red Book®*.

- Ignore "HCFA" [Health Care Financing Administration]. This entry is not a manufacturer but refers to federal price information. "REPACK" under a company name indicates that the company repackages the brand-name drug that heads the listing but does not manufacture it.

- Refer to the Manufacturer Directory under "Manufacturer/ Wholesaler Info" to obtain the name, address, and contact information of the manufacturer.

- Contact the manufacturer to find out where the product is manufactured (the origin).

Example: Checking the Availability of Co-Trimoxazole Double-Strength Tablets from a U.S. Source Using the 2001 *Drug Topics® Red Book®*

Co-trimoxazole is a combination of trimethoprim and sulfamethoxazole; "double-strength" (DS) refers to tablets that contain trimethoprim 160mg/sulfamethoxazole 800mg. A well-known trade name in the United States for this combination is Septra. Searching for "Septra" in the Rx Products listing brings up a generic name of "smz/tmp."

Searching in the 2001 edition under "smz/tmp" gives a total of 26 U.S. sources for co-trimoxazole double-strength tablets, 3 of which are listed by brand name.

The Manufacturer Directory entry for Monarch Pharmaceuticals, one of the manufacturers of co-trimoxazole double-strength tablets (brand-name Septra DS tablets), lists the telephone number as 1-800-776-3637.

Information obtained from the medical information department at Monarch is that the product is manufactured in the United States and is therefore of U.S. origin.

FDA Web site

Using the FDA Web site to check the availability of drugs from U.S. sources offers the advantages of being easily accessible if Internet access is available and of providing the most current information on FDA approvals. In addition, existing U.S. patent information can be checked at the same time, except for the most recently approved products.

The main disadvantage of using the FDA site is that the pharmaceutical company that originally applied for FDA approval for each product is listed, but the current manufacturer is not. You need to contact the applicant to find the current manufacturer and, in turn, the origin of the product. In addition, contact information for the applicant is not given, although this information generally can be obtained from the Pharmaceutical Research and Manufacturers of America (PhRMA) membership list. Two databases need to be searched to ensure that you have the most current information on FDA approvals. Some categories of drugs, including drugs approved before 1938, and many OTC drugs are not included. If you cannot locate the drug that you are searching for, you may send an E-mail to the FDA at **druginfo@cder.fda.gov** requesting the information.

If you are procuring many products, it may be easier to approach U.S. wholesalers (see previous section).

How to use the FDA Web site

The following Web-site addresses were current as of December 20, 2001. Addresses to Web-site pages can change as Web sites are updated. If the Web site is listed as unavailable, begin your search from the FDA home page **www.fda.gov/**. Under "Products FDA Regulates" click on "Drugs" and then on "Orange Book."

- Go to **www.fda.gov/cder/ob/docs/queryai.htm** to search by active ingredient (use generic name) in the latest edition of the FDA *Orange Book*[12] [accessed December 20, 2001]. If your product has more than one active ingredient, for example Combivir (lamivudine/zidovudine), you can use either active ingredient to locate the product. You can choose to search under the Rx (U.S. prescription drug products) listing or OTC (U.S. over-the-counter drug products) listing. If you are not sure of the U.S. classification for the drug, search both categories. You do not need to put in the entire generic name. For example, for penicillin G benzathine, "penicillin" will suffice.

- A table will appear with a list of FDA-approved products that contain that drug. Find the product (dosage form/ route/strength) that you wish to procure.

- The final column lists the applicant, which is the pharmaceutical company that applied for FDA approval for that product. The applicant may not necessarily be the current manufacturer, but you can contact the applicant to find out the current manufacturer.

- At this point you can also check if there are any unexpired U.S. patents on any FDA-approved products (see Section C6) by clicking on "Appl No" (first column) and then clicking on "Patent and Exclusivity Info for this product" (bottom line of column). The top section of the next page has information on existing U.S. patents. Ignore "Exclusivity Information."

[12] The *Orange Book* lists all FDA-approved prescription drugs, including new and generic drugs. It is updated monthly.

- Finally, check the most recent FDA drug approvals on **www.fda.gov/cder/approval/index.htm** by alphabetical listing of generic names [accessed December 20, 2001]. Ignore any products that that are "tentatively approved." It is not possible to obtain U.S. patent information from this database.

- Contact the applicant to find out the current manufacturer of the product and the country where it is produced. The contact information for the applicant can be obtained from **http://www.phrma.org/who/memlist.phtml** (the Pharmaceutical Research and Manufacturers of America [PhRMA] membership list) [accessed December 20, 2001] or from the Manufacturer Directory in the *Drug Topics® Red Book®* (see previous section).

- Some categories of drugs, including drugs approved before 1938, and many OTC drugs are not listed in the *Orange Book*. If you cannot locate the drug that you are searching for, you may send an E-mail to the FDA at **druginfo@cder.fda.gov** requesting the information.

Example: Checking the Availability of Nevirapine Tablets 200mg from a U.S. Source

Searching www.fda.gov/cder/ob/docs/queryai.htm on December 20, 2001, for "nevirapine" in Rx database brings up only one entry for nevirapine tablets 200mg, trade name Viramune and applicant Boehringer Ingelheim.

Clicking on the "Appl No"—020636— and then clicking on "Patent and Exclusivity Info for this product" gives the information that a U.S. patent exists for this product and that it expires November 22, 2011.

Searching http://www.phrma.org/who/memlist.phtml for Boehringer Ingelheim gives the U.S. telephone number of 1-203-798-9988.

Information obtained from medical information at Boehringer Ingelheim is that the current manufacturer of Viramune is Roxane and that the product is manufactured in the United States.

4. Drugs, checking availability from non-U.S. sources

In this section, sources that can be used to check the availability of drugs from non-U.S. sources are described, namely, contacting international pharmaceutical suppliers/ agencies, manufacturers, and local suppliers. This section is not intended to be comprehensive, and supplier information is used for illustration and does not imply that these suppliers are endorsed or preferred over others by USAID or RPM Plus.

Contacting international pharmaceutical suppliers/agencies

International pharmaceutical suppliers/agencies can be contacted directly to obtain information on the availability of drug products from non-U.S. sources.

The MSH *International Drug Price Indicator Guide*[13] can be used to locate selected international suppliers/agencies that listed a price for the product you wish to procure at the time that the price guide was prepared. The *International Drug Price Indicator Guide* is available at **http://erc.msh.org**. Click on "International Drug Price Indicator Guide" listed under "Quick Links to popular ERC resources." Contact the international supplier directly to confirm availability of the product. The contact information for the international suppliers/agencies listed in the *International Drug Price Indicator Guide* is in Annex 10.

Contacting the manufacturer

Contact the manufacturer directly to request information on availability from non-U.S. sources including, for example, the country of origin if manufactured outside of the United States, or from suppliers in the cooperating country itself.

The Web sites of manufacturers frequently give contact information for company offices in different regions of the world that can be contacted directly to obtain information on the availability of the product from sources outside of the United States.

[13] The *International Drug Price Indicator Guide* is maintained by the Center for Pharmaceutical Management of MSH and is an indication of generic drug prices on the international market. This guide provides a spectrum of prices from nonprofit drug suppliers and procurement agencies, based on their current catalogues or price lists. The guide is intended for reference only and the vendor must be contacted directly to order products.

Contacting local wholesaler/supplier in cooperating country

The ministry of health, the USAID field office, the drug regulatory authority, or the pharmaceutical or medical association in the cooperating country can be contacted with a request for a list of reliable and reputable wholesalers/ suppliers who are known to supply drugs of acceptable safety, efficacy, and quality. See Section E3 on USAID requirements to assure quality, safety, and efficacy of non-FDA-approved drug products.

Contact the wholesaler/supplier to request information on the availability of the drug product and the country of origin.

5. Pharmaceutical products other than drugs and HIV test kits, checking availability from U.S. sources

Two methods of checking the availability of pharmaceutical products other than drugs and HIV test kits from U.S. sources are described, namely, contacting U.S. wholesalers and contacting the FDA.

Contacting U.S. wholesalers

Contacting U.S. wholesalers is often the easiest method to check the availability of pharmaceutical products other than drugs and HIV test kits. Information on origin, price, pack size, whether the product has FDA approval, and existing U.S. patents can be requested at the same time.

How to obtain information from U.S. wholesalers

A list of U.S. wholesalers is not currently available on the Internet. However, the *Drug Topics® Red Book®*[14] contains a Pharmaceutical Wholesaler Directory, and a copy from the 2001 edition is included in Annex 13.

Contact two or three wholesalers and request information on the availability of each product from U.S. sources.

[14] See note 8.

Contacting the FDA

The FDA can supply information on the availability of FDA-approved products. However, the FDA Web site is difficult to use for pharmaceutical products other than drugs and HIV, HTLV, and hepatitis test kits. It is easier and more accurate to contact the FDA directly for information on other products. Information on the availability of FDA-approved HTLV and hepatitis test kits can be obtained from the FDA Web site as described for HIV test kits in Section B1.

The main disadvantage of this method is that the FDA can provide information on the company that originally applied for FDA approval for each product but not the current manufacturer. You will therefore need to contact the applicant to find the current manufacturer and, in turn, the origin of the product.

How to obtain information from the FDA

Information on the availability of FDA-approved biological products (including vaccines) can be obtained by—

- Telephoning the FDA Center for Biologics Evaluation and Research (CBER) on 1-301-827-1800 or 1-800-835-4709
- Sending an E-mail request to FDA Consumer Affairs Branch at **octma@cber.fda.gov**

Using the information from the FDA, contact the applicant to request information on the current manufacturer and availability.

6. Pharmaceutical products other than drugs and HIV test kits, checking availability from non-U.S. sources

International pharmaceutical suppliers/agencies, manufacturers, and local suppliers can be contacted to check the availability of pharmaceutical products other than drugs and HIV test kits from non-U.S. sources. This section is not intended to be comprehensive, and supplier information is used for illustration and does not imply that these suppliers are endorsed or preferred over others by USAID or RPM Plus.

Contacting international pharmaceutical suppliers/agencies

International pharmaceutical suppliers/agencies can be contacted directly to obtain information on the availability of pharmaceutical products from non-U.S. sources. The contact information for the international suppliers/agencies listed in the MSH *International Drug Price Indicator Guide* is in Annex 10.

Contacting the manufacturer

Contact the manufacturer to request information on the availability of the product from non-U.S. sources including, for example, the country of origin if manufactured outside of the United States, or from suppliers in the cooperating country itself.

The Web sites of manufacturers frequently give contact information for company offices in different regions of the world that can be contacted directly to obtain information on the availability of their product from sources outside of the United States.

Contacting local wholesalers/suppliers in the cooperating country

The ministry of health, a USAID field office, the national AIDS committee, or the national regulatory authority in the cooperating country can be contacted with a request for a list of reliable and reputable wholesalers/suppliers who are known to supply pharmaceutical products of acceptable safety, efficacy, and quality. See Section E4 on USAID requirements to assure quality, safety, and efficacy of non-FDA-approved pharmaceutical products other than drugs and HIV test kits.

Contact the wholesaler/supplier directly to request information on the availability of the product along with information on the country of origin of the product.

Section C

Criteria for approval of a source/origin waiver

To obtain approval to procure non–U.S. source and/or origin pharmaceutical products, USAID Missions and CAs must satisfy M/OP that procurement of a U.S. source and/or origin product in the same or substantially equivalent form has been considered and justify the necessity of purchasing a non–U.S. source and/or origin product. The regulations relevant to this section are described in Chapter 2.

To obtain approval to procure pharmaceutical products under a source/origin waiver, you must satisfy M/OP that—

- The product is essential to the activity.

AND

- The pharmaceutical product in the same or substantially equivalent form is unavailable from U.S. sources **OR** the lowest available delivered price from the United States is reasonably estimated to be 50 percent or more higher than the delivered price from another source.

AND

- The pharmaceutical product meets the standards of the U.S. FDA or other controlling U.S. authority **OR** information is available to attest to the safety, efficacy, and quality of the product.

AND

- Procurement from non-U.S. sources will not infringe a U.S. patent.

AND if applicable

- Procurement from non-U.S. sources is necessary to promote efficiency in the use of foreign assistance resources, including to avoid impairment of foreign assistance objectives.

AND if applicable

- Procurement in a country not normally eligible is necessary to meet unforeseen circumstances, such as emergency situations.

In Section C each of the criteria for justifying procurement of non–U.S. source and/or origin pharmaceutical products is discussed, and sources of information and examples are given as appropriate.

Use as many criteria as are applicable in your request to procure non–U.S. source and/or origin pharmaceutical products, but ensure that the justification under each criterion is relevant to the pharmaceutical products that you wish to procure. Refer to the sample requests included in Annexes 8 and 9 for suggestions on a format for this section of your request.

Contents of Section C

1. *The non–U.S. source and/or origin product is essential to the activity*
2. *The pharmaceutical product is unavailable from U.S. sources*
3. *The delivered price of the product from the United States is 50 percent or more higher than from another source*
4. *The non–U.S. source and/or non–U.S. origin product is FDA approved*
5. *Information is available to attest to safety, efficacy, and quality of non-FDA-approved, non–U.S. source and/or origin products*
6. *No U.S. patents are infringed by procurement from non-U.S. sources*
7. *Procurement of the non–U.S. source and/or non–U.S. origin product promotes efficient use of foreign assistance resources*
8. *Procurement of the non–U.S. source and/or non–U.S. origin product is necessary due to unforeseen circumstances*

1. The non–U.S. source and/or origin product is essential to the activity

USAID regulations require that the procurement of non–U.S. source and/or origin pharmaceutical products with USAID funding be permitted only for products that are essential to the activity.

Briefly describe the relevant objectives in the scope of work for the contract/agreement/grant and explain how procurement of the pharmaceutical product is essential to fulfill those objectives. References can be included as appropriate.

Example: Rapid HIV Test Kits for an HIV Voluntary Counseling and Testing (VCT) Program in Zimbabwe—Justification That the Product Is Essential to the Activity

Under the approved USAID/Harare AIDSMark scope of work, Population Services International is required to provide a VCT service in Zimbabwe.

HIV testing is a primary and essential service and HIV test kits are needed for the VCT program. HIV counseling is valuable and helps clients to adopt risk reduction behaviors, but few clients would come for counseling alone if testing were unavailable.

This program plans to use rapid HIV test kits for same-day HIV testing because studies have shown that a significant number of clients do not return to collect their results. For example, in a survey of ten selected African urban sites, 92% of pregnant women accepted to be tested (range: 77–99%), but only 70% (range: 33–100%) returned for their test result.[1]

[1] M. Cartoux, N. Meda, P. Van de Perre, et al. Acceptability of Voluntary HIV Testing by Pregnant Women in Developing Countries: An International Survey. 1997. *AIDS 1998*, 12: 1571–80.

2. The pharmaceutical product is unavailable from U.S. sources

USAID regulations state that procurement of a pharmaceutical product from non-U.S. sources may be permitted if the product in the same or substantially equivalent form is unavailable from U.S. sources. Although not stated specifically in the USAID regulations, lack of availability can also be used to justify procurement of a non–U.S. origin product.

"A substantially equivalent form" is not defined in the USAID regulations, and USAID Missions/CAs are expected to build a compelling argument as to why the available U.S. source and/or U.S. origin pharmaceutical product is not "substantially equivalent." In some circumstances, a substantially equivalent pharmaceutical product may be required not only to contain the same active ingredient in the same dosage form and strength, but also to have the same bioavailability. Bioavailability refers to the speed and completeness with which a drug administered in a specific form enters the bloodstream. For example, the bioavailability of rifampin when combined with other antitubercular drugs to treat tuberculosis can vary significantly among different products. Alternatively, the pharmaceutical product may simply need to have the same therapeutic moiety and a different salt, dosage form, or strength to be acceptable.

Check the availability of the pharmaceutical product in the same and "substantially equivalent" forms from U.S. sources, and then build a compelling argument why these products should not be considered to be substantially equivalent to the non–U.S. source and/or origin product that you wish to buy. Refer to Section B on procedures that can be used to check the availability of pharmaceutical products from U.S. sources.

M/OP will accept that a pharmaceutical product is unavailable if the manufacturer or supplier is unwilling or unable to supply the product or to fulfill the whole order. However, you will be expected to justify that the quantity ordered is reasonable and to provide a compelling argument why phased deliveries are unacceptable.

3. The delivered price of the product from the United States is 50 percent or more higher than from another source

USAID regulations state that procurement of a pharmaceutical product from non-U.S. sources may be permitted if the lowest available delivered price from the United States is reasonably estimated to be 50 percent or more higher than the delivered price from another source.

The delivered price of a pharmaceutical product includes storage and delivery charges, duty, taxes, and tariffs. In general, USAID-funded procurements must be transported on U.S. ocean/air flag carriers and therefore delivery charges must include transportation on U.S. flag carriers (see Chapter 3 Section F2).

Price quotes from U.S. wholesalers can be used as the comparison price. Contact two or three U.S. wholesalers and request delivered price quotes using U.S. flag carriers for the pharmaceutical products that you are requesting approval to procure. Use the lowest quote as the comparison price to justify procurement from non-U.S. sources. The delivered price for the non–U.S. source product must similarly include delivery by a U.S. flag carrier. A list of U.S. wholesalers is not currently available on the Internet. However, the *Drug Topics® Red Book®*[15] contains a Pharmaceutical Wholesaler Directory, and a copy from the 2001 edition is included in Annex 13.

4. The non–U.S. source and/or non–U.S. origin pharmaceutical product is FDA approved

Pharmaceutical products procured with USAID funding either must be FDA approved or information must be available to attest to the safety, efficacy, and quality of the product. FDA approval means that the product has met the standards of the U.S. Food and Drug Administration for safety, efficacy, and quality for the proposed application.

Refer to Section D on how to check if a pharmaceutical product is FDA approved.

Include a statement in the request that the product is FDA approved for the proposed application.

5. Information is available to attest to safety, efficacy, and quality of non-FDA-approved, non–U.S. source and/or non–U.S. origin products

Pharmaceutical products procured with USAID funding either must be FDA approved or information must be available to attest to the safety, efficacy, and quality of the product. If the product is not FDA approved, you must provide information to M/OP/TC/COM to attest that the pharmaceutical product is safe and efficacious for the proposed application and also that the quality of the product meets acceptable standards and has been manufactured in accordance with acceptable manufacturing practice requirements.

[15] See note 8.

Refer to Section E for a description of the kind of information to be submitted with your request for approval to procure a non-FDA-approved pharmaceutical product to attest to its safety, efficacy, and quality and for possible sources for obtaining the information.

6. No U.S. patents are infringed by procurement from non-U.S. sources

USAID regulations state that USAID-funded procurement of pharmaceutical products from non-U.S. sources must not infringe any U.S. patent. You must, therefore, include a statement to the effect that no U.S. patents will be infringed or that the express permission of the owner of the patent has been obtained. In addition, you can include a statement that the manufacturer/supplier will be required to certify on the invoice that the items supplied do not infringe any U.S. patents.

How to check for U.S. patents for drug products

Three methods are described for checking for U.S. patents on drug products, namely, using the FDA Web site, contacting the FDA, and contacting the manufacturer/supplier.

Using the FDA Web site

The *Orange Book*[16] on the FDA Web site can be used to check the U.S. patent status for most drugs. However, the *Orange Book* is not a complete listing of all drugs. Drugs approved prior to 1938 and many over-the-counter (OTC) products, such as acetaminophen (Tylenol) 325mg tablets, are not included. Contact the FDA directly for U.S. patent information if you cannot find a drug in the *Orange Book*.

How to use the FDA Web site

The following Web-site addresses were current as of December 20, 2001. Addresses to Web-site pages can change as Web sites are updated. If the Web site is listed as unavailable, begin your search from the FDA home page **www.fda.gov/**. Under "Products FDA Regulates" click on "Drugs" and then on "Orange Book."

[16] The *Orange Book* lists all FDA-approved prescription drugs, including new and generic drugs. It is updated monthly.

- To search by active ingredient, go to **www.fda.gov/cder/ob/docs/queryai.htm** in the latest edition of the FDA *Orange Book* (use generic name). If the product has more than one active ingredient, such as Combivir (lamivudine/zidovudine), use either generic name to locate the product. You can choose to search under the Rx (U.S. prescription drug products) listing or the OTC (U.S. over-the-counter drug products) listing. If you are not sure of the U.S. classification for the drug, search both categories. You do not need to put in the entire generic name; for example, for penicillin G benzathine, "penicillin" will suffice. A table will appear with a list of FDA-approved products that contain that drug. Find the product (dosage form/route/strength) that you wish to check.

- To search by proprietary name, go to **www.fda.gov/cder/ob/docs/querytn.htm** in the latest edition of the FDA *Orange Book*. A table will appear with a list of FDA-approved products with that brand name. Find the product (dosage form/route/strength) that you wish to check.

- Click on "Appl No" (first column) and then click on "Patent and Exclusivity Info for this product" (bottom line of column). The top section of the next page has information on existing U.S. patents. Ignore "Exclusivity Information."

Example: Checking for U.S. Patents for Ciprofloxacin 500mg tablets

- Searching www.fda.gov/cder/ob/docs/queryai.htm on December 20, 2001, for "ciprofloxacin" in the Rx database brings up only one entry for ciprofloxacin tablets 500mg, trade name Cipro and applicant Bayer.

- Clicking on the "Appl No"—19537— and then clicking on "Patent and Exclusivity Info for this product" gives the information that two U.S. patents exist for this product that expire December 9, 2003, and February 15, 2011, respectively.

Contacting the FDA

Information on the U.S. patent status of drug products can be obtained by either a telephone or E-mail request to the FDA.

- Telephone the FDA Drug Evaluation and Research (CDER), Drug Information Department, on 1-301-827-4570 to request information on unexpired U.S. patents for a drug product.

- Send a request to FDA CDER Drug Information Department at **druginfo@cder.fda.gov** to request information on unexpired U.S. patents for a drug product.

Contacting the manufacturer/supplier

The manufacturer/supplier of the drug product can be contacted and asked if procurement of the product will infringe any U.S. patents. In addition, you can request that the manufacturer/supplier certify on the invoice that the items supplied do not infringe any U.S. patents.

How to check for U.S. patents for pharmaceutical products other than drugs

The easiest method to check if procurement of pharmaceutical products other than drugs from a non-U.S. source will infringe an existing U.S. patent is to contact the manufacturer/supplier of the product and request the information. In addition, you can request that the manufacturer/supplier certify on the invoice that the items supplied do not infringe any U.S. patents.

7. Procurement of the non–U.S. source and/or non–U.S. origin product promotes efficient use of foreign assistance resources

Under USAID regulations, promoting efficiency in the use of foreign assistance resources, including to avoid impairment of foreign assistance objectives, can be used to further justify procurement of a pharmaceutical product from non-U.S. sources where the criteria discussed previously are fulfilled. Include a brief statement in your request for approval explaining how this criterion is relevant to the pharmaceutical products that you wish to procure. Some examples of justifications under this criterion that could be relevant to pharmaceutical procurement are included below.

Efficiency in the use of foreign assistance resources

Efficiency in the use of foreign assistance resources could be achieved by procuring a product from non-U.S. sources that is substantially cheaper than a U.S. source product and/or has reduced costs associated with its use. The reduced cost of the non–U.S. source product and/or of costs associated with its use would therefore allow the services in the scope of work to be provided to more clients/patients.

For example, reduced costs can be associated with procuring a non–U.S. source rapid HIV test kit in preference to a U.S. source rapid HIV test kit. Costs associated with retraining of technical staff to use a product they are unfamiliar with, translating instructions into the local language, and providing refrigerated storage conditions or transportation of blood supplies to laboratories for testing may be avoided. The characteristics of the non–U.S. source product can increase the efficiency of the program by providing the service to more clients/patients; for example, using rapid HIV test kits can allow same-day HIV testing that would increase program efficiency by providing test results to those patients who would not normally return.

Avoiding impairment of foreign assistance objectives

Avoiding impairment of foreign assistance objectives could include enhancing the sustainability of the program after transfer of funding to the host country. The compatibility of the product with country guidelines/essential drugs lists, the reduced cost of the non–U.S. source pharmaceutical product and of additional equipment and supplies, and its appropriateness for the local context and local technical capacity would all contribute to enhancing sustainability.

8. Procurement of the non–U.S. source and/or non-U.S. origin product is necessary due to unforeseen circumstances

Under USAID regulations, unforeseen circumstances such as emergencies can be used to further justify procurement of a pharmaceutical product from non-U.S. sources, where the criteria discussed previously are fulfilled. However, the justification that procurement in a country not normally eligible is necessary to meet unforeseen circumstances, such as emergency situations, is not generally applicable to the procurement of HIV/AIDS-related pharmaceutical products.

Section D

Checking whether a pharmaceutical product is FDA approved

Pharmaceutical products procured with USAID funding either must be FDA approved or information must be available to attest to the safety, efficacy, and quality of the product. FDA approval means that the product has met the standards of the U.S. Food and Drug Administration for safety, efficacy, and quality for the proposed application. Section D describes procedures and sources of information that can be used to check whether a pharmaceutical product is approved by the FDA for the proposed application.

Contents of Section D

1. HIV test kits, checking whether a product is FDA approved

Using the FDA Web site, contacting the manufacturer/ supplier, and contacting the FDA are methods that can be used to check the FDA approval status of HIV test kits.

Using the FDA Web site

The FDA Web site can be used to check whether an HIV test kit is FDA approved. This procedure can also be used to check the FDA approval status of HTLV and hepatitis test kits. The following Web-site addresses were current as of December 20, 2001. Addresses to Web-site pages can change as Web sites are updated. If the Web site is listed as unavailable, begin your search from the FDA home page **www.fda.gov/**. Under "Products FDA Regulates" click on "Biologics" and then click on "Products." Click on "HIV/Hepatitis Tests" to find the list of Licensed/Approved HIV, HTLV, and Hepatitis Tests.

Search Licensed/Approved HIV, HTLV, and Hepatitis Tests at **www.fda.gov/cber/products/testkits.htm** [accessed December 20, 2001]. If the test kit appears in the list, then it is FDA approved. This document is current and is updated when an HIV, HTLV, or hepatitis test kit is approved.

Contacting the manufacturer/supplier

Contact the manufacturer/supplier and ask if the HIV test kit is FDA approved. You can also ask the manufacturer/supplier to certify that the product is FDA approved on the invoice.

Contacting the FDA

You can contact the FDA to check whether an HIV test kit has been approved by the FDA by—

- Telephoning the FDA Center for Biologics Evaluation and Research (CBER) on 1-301-827-1800 or 1-800-835-4709
- Sending a request to FDA Consumer Affairs Branch at **octma@cber.fda.gov**

2. Drugs, checking whether a product is FDA approved

Most drugs available from **U.S. sources** are FDA approved. However, some U.S. manufacturers produce drug products solely for export that are not FDA approved. Two methods are described to confirm that the drug is FDA approved, namely, contacting the supplier/manufacturer or contacting the FDA.

You cannot assume that a drug product procured from **non-U.S. sources** is FDA approved even if the same product made by the same manufacturer is available for sale in the United States. A pharmaceutical manufacturer can have several manufacturing plants in different countries all making the same product, and only the product manufactured, for example, in the U.S.-based plant may be FDA approved. The FDA approval status of non–U.S. source drug products can be checked by requesting the information from the manufacturer/supplier.

Contacting the manufacturer/supplier

Contact the manufacturer/supplier and ask whether the product is FDA approved for the proposed application. You can also ask the manufacturer/supplier to certify that the drug product is FDA approved on the invoice.

Contacting the FDA

You can contact the FDA to check whether a drug product has been approved by the FDA for the proposed application by—

- Telephoning the FDA Drug Evaluation and Research (CDER), Drug Information Department on 1-301-827-4570
- Sending a request to FDA CDER Drug Information Department at **druginfo@cder.fda.gov**

3. Pharmaceutical products other than drugs and HIV test kits, checking whether a product is FDA approved

Contact the manufacturer/supplier or contact the FDA to check the FDA approval status of pharmaceutical products other than drugs and HIV test kits.

To check the FDA approval status of HTLV and hepatitis test kits, follow the procedure described in the previous section for HIV test kits.

Contacting the manufacturer/supplier

Contact the manufacturer/supplier and ask whether the product is FDA approved for the proposed application. You can also ask the manufacturer/supplier to certify that the product is FDA approved on the invoice.

Contacting the FDA

Information on the FDA approval status of biological products (including vaccines) can be obtained by—

- Telephoning the FDA Center for Biologics Evaluation and Research (CBER) on 1-301-827-1800 or 1-800-835-4709
- Sending a request to FDA Consumer Affairs Branch at **octma@cber.fda.gov**

Section E

Information to attest to the safety, efficacy, and quality of non-FDA-approved products

In the United States, the safety, efficacy, and quality of pharmaceutical products is assured through a rigorous program of testing and evaluation by the FDA. In addition, pharmaceutical manufacturing facilities of FDA-approved products undergo thorough inspections and are required to maintain Good Manufacturing Practice (GMP) standards.

To obtain approval to procure a non-FDA-approved pharmaceutical product, you will need to provide information to attest that the product is safe and efficacious for the proposed application and that the quality of the product meets acceptable standards and has been manufactured in accordance with acceptable manufacturing practice requirements. The importance of assuring that non-FDA-approved products are safe, efficacious, and of acceptable quality cannot be overemphasized. The potential liability of USAID and loss of credibility as a consequence of a serious side or adverse effect, a lack of therapeutic effect, or a toxic effect of a USAID-funded pharmaceutical product could be considerable. The prevalence of poor-quality drugs is difficult to determine, but problems are known to be significant in many parts of the world, especially in developing countries. In addition, the issue of counterfeit drugs is a growing concern. Consequently, steps must be taken to assure the use of reputable suppliers and manufacturers, and documentation obtained to attest to the quality of pharmaceutical products.

This section describes the kind of information that is necessary to submit with your request for approval to procure a non-FDA-approved product to attest to the safety, efficacy, and quality of the product as well as possible sources for obtaining such information. It must be understood this information will vary according to a number of factors, including the category of pharmaceutical product, its proposed use, and previous USAID experience in procuring and using the product. Therefore, this section should be used solely as a guideline. Consult your CTO for further guidance.

Contents of Section E

1. HIV test kits

Information to attest to safety, efficacy, and quality

The following list presents examples of the kind of information that M/OP/TC/COM will expect you to submit with your application to procure non-FDA-approved HIV test kits not listed in Tab 1 of the HIV test kit source/origin waiver.

Regulatory information on the product

The safety and efficacy of a pharmaceutical product can usually be established if it is marketed in countries whose regulatory authorities are recognized as being effective. WHO recommendations for quality assurance include a requirement that a pharmaceutical product have a valid marketing authorization in the country in which it is produced.

- Does the HIV test kit have valid marketing authorization in—
  - Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa?

- The European Union or a country in the European Economic Area?
- The country in which it is produced? Request a certificate from the manufacturer stating that the pharmaceutical product is available for sale in the country of manufacture and submit it with your request.
- The cooperating country? Request certification from the cooperating country and submit it with your request.

- Does the HIV test kit require special storage or operating conditions to maintain quality?
- Does the cooperating country provide laboratory testing of the HIV test kit that confirms that it meets selected reference standards?
- Is the HIV test kit included in the cooperating country's HIV testing algorithm or guidelines? If yes, provide certification to verify inclusion.

Expert opinion on the product

Information on safety and efficacy can also be obtained from recognized experts in the field and from reputable current publications and textbooks. In 1988, WHO initiated a program to provide objective assessments of commercially available assays for detecting antibodies to HIV-1 and HIV-2. This program continues today and provides valuable information to countries in need of unbiased performance data for HIV testing kits. CDC complements the activities of WHO by providing consultation and assistance to evaluate HIV test kits to determine an appropriate testing methodology and algorithm to be used in a particular health care setting.

- Has the performance of the HIV test kit been evaluated? If yes, by whom? Include data from the evaluation such as sensitivity, specificity, HIV variant/subtype detected, and testing principle.
- Has the testing algorithm/guidelines been evaluated and approved at country level? If yes, by whom? Include certification verifying that the product/testing algorithm has been evaluated and approved at country level by CDC, WHO, and/or the cooperating country.

Experience using the product

M/OP/TC/COM will be particularly interested in the experience of USAID or any other U.S. government (U.S.G.) agency in using the HIV test kit.

- Does USAID, including Bureau of Humanitarian Response, Office of Foreign Disaster Assistance (BHR/OFDA), or any other U.S.G. agency (e.g., CDC, U.S. Army) have any prior history or experience using the HIV test kit? Has the agency experienced any problems with the safety, efficacy, or quality of the product?

- Has the HIV test kit been approved by M/OP/TC/COM for use by any other USAID Mission or CA?

- Does the cooperating country have any prior history or experience using this HIV test kit? Has the country experienced any problems with the safety, efficacy, or quality of the product?

- Have problems with the safety, efficacy, or quality of the HIV test kit been reported since it was first marketed?

Information on the manufacturer

It is important to select reputable manufacturers that have a history of supplying good-quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring pharmaceutical products from the manufacturer? Has the agency experienced any problems with the quality of HIV test kits supplied?

- Does the cooperating country have any prior history or experience procuring pharmaceutical products from the manufacturer? Has it experienced any problems with the quality of HIV test kits supplied?

- Has the manufacturing site recently been inspected for Good Manufacturing Practice by the U.S. FDA or any other international inspection agency and/or by the resident country's regulatory/governing authority? Request a copy of the GMP certificate or the WHO-type Certificate of Pharmaceutical Product from the manufacturer or the issuing regulatory authority and submit this with your application. The extent to which this certificate will assure the quality of the manufacturing facilities or processes will depend on the competency of the issuing regulatory authority.

- Is the manufacturer able to supply a batch certificate or certificate of analysis for the HIV test kit that shows that it meets reference standards? Include a statement that the manufacturer will be requested to provide this certificate with the invoice.

Information on the supplier (if different from the manufacturer)

It is important to select reputable suppliers and distributors that have a history of supplying good-quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring pharmaceutical products from the supplier? Has the agency experienced any problems with the quality of the products supplied?

- Does the cooperating country have any prior history or experience procuring pharmaceutical products from the supplier? Has the country experienced any problems with the quality of the products supplied?

- Have the measures that the supplier takes to assure the safety, efficacy, and quality of the pharmaceutical products it supplies been evaluated by USAID or any other U.S.G. agency and found to be acceptable?

Where to obtain information to attest to safety, efficacy, and quality of HIV test kits

This section describes some sources from which to obtain information to attest to the safety, efficacy, and quality of pharmaceutical products.

Manufacturer/supplier

You should be aware that information provided by a manufacturer may be biased in its presentation. All information provided should be evaluated carefully and supported by information from independent sources if possible. Your CTO can advise you on this subject.

The manufacturer/supplier can be contacted directly and asked to supply the following information. Contact information for manufacturers of selected HIV test kits is listed in Annex 11.

- Information on valid marketing authorizations
- Certification that the HIV test kit is available for sale in the country of manufacture
- Information on special storage or operating conditions needed to maintain quality
- Information on the safety and efficacy of HIV test kit and problems reported since the product was first marketed
- Certificate of Good Manufacturing Practice or WHO-type Certificate of Pharmaceutical Product
- Batch certificate or certificate of analysis
- Information on whether the HIV kit is included in an approved testing algorithm/guidelines
- Information on evaluation of the performance of the HIV test kit

Cooperating country

The following information may be requested from the appropriate cooperating country ministry of health (MOH) procurement unit, national regulatory authority, and/or national AIDS committee.

- Information and certification that the HIV test kit is registered for use in the cooperating country
- Experience using the product/supplier/manufacturer and any reported problems
- Information on whether the HIV kit is included in an approved HIV testing algorithm/guidelines
- Information on the evaluation/approval of the HIV testing algorithm/guidelines and approving authority/ organization
- Information on evaluation of the performance of the HIV test kit
- Certification that the HIV test kit is included in the cooperating country testing algorithm/guidelines that have been evaluated locally and approved by CDC, WHO, and/or the cooperating country

WHO

WHO periodically evaluates enzyme-linked immunosorbant assays (ELISAs) and simple/rapid HIV test kits that are available for bulk purchase by the public sector. Results of these evaluations are available in Comparative Evaluation of the Operational Characteristics of Commercially Available Assays to Detect Antibodies to HIV-1 and/or HIV-2 in Human Sera from **http://www.who.int/pht/blood_safety/hivkits.html** [accessed December 20, 2001].

CDC

Contact information for CDC is available in Annex 12. CDC officials should be able to provide the following information:

- Information on whether the HIV kit is included in CDC-approved cooperating country testing algorithm/ guidelines
- Information on the evaluation/approval of the HIV testing algorithm/guidelines by CDC
- Certification that the HIV test kit is included in the cooperating country testing algorithm/guidelines that have been evaluated locally and approved by CDC
- Information on evaluation of the performance of the HIV test kit
- Information on special storage or operating conditions needed to maintain quality

In addition, information on the evaluation of the performance of selected rapid HIV test kits and special storage conditions can be obtained from the following publication. "Rapid Tests for HIV Antibody" prepared by Dr. Bernard M. Branson from CDC summarizes data on the characteristics and performance of rapid HIV tests from peer-reviewed journals and conference abstracts. Data from test manufacturers are not included unless corroborated by independent evaluations. This article is available from *AIDS Reviews 2000,* 2: 76–83, and is also currently on the Web site **http://www.medadvocates.org/cdc/ rapidtest.html** [accessed December 20, 2001].

CTO

Your CTO should be able to direct you to the appropriate source to provide the following information:

- Experience of other USAID Missions, departments (including BHR/OFDA), and U.S.G. agencies using product/manufacturer/supplier and any problems reported
- Information on whether the HIV test kit has been approved by M/OP/TC/COM for use by any other USAID Mission or CA for the proposed indication
- Information on USAID (including BHR/OFDA) or any other U.S.G. agency evaluation of the supplier and measures taken by the supplier to assure safety, efficacy, and quality of products supplied

Recognized experts in field

Information on the safety and efficacy of HIV test kits and reported problems since the product was first marketed can be located by consulting reputable textbooks or publications, seeking expert opinion, or by conducting a literature search.

2. Drugs

Information to attest to safety, efficacy, and quality

The following list presents examples of the kind of information that M/OP/TC/COM will expect you to submit with your application to procure non-FDA-approved drugs.

Regulatory information on the product

The safety and efficacy of a drug product can usually be established if it is marketed in countries whose regulatory authorities are recognized as being effective. WHO recommendations for quality assurance include a requirement that a pharmaceutical product have a valid marketing authorization in the country in which it is produced. Cooperating countries with drug registration systems normally require that all drugs imported into a country be registered locally.

- Does the drug product have valid marketing authorization for the proposed indication in—

- Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa?
- The European Union or a country in the European Economic Area?
- The country in which it is produced? Request a certificate from the manufacturer stating that the pharmaceutical product is available for sale in the country of manufacture and submit it with your request.
- The cooperating country? Request certification from the cooperating country and submit it with your request.

- Does the drug product require special storage or operating conditions to maintain quality?
- Does the cooperating country provide laboratory testing of the drug product that confirms that it meets selected pharmacopeia or other reference standards?
- Is the drug included in the cooperating country's Essential Drugs List/Formulary for the proposed indication?
- Is use of the drug described in standard treatment guidelines of the cooperating country for the proposed indication?

Expert opinion on the product

Information on safety and efficacy can also be obtained from recognized experts in the field and from reputable current publications and textbooks.

- Is the drug recognized as being safe and efficacious and recommended for the proposed application by recognized experts in the field, for example, CDC or WHO?
- Is published data in a reputable peer-reviewed journal by recognized experts in the field available to support the safety and efficacy of the drug for the proposed application?
- Is the drug product on the WHO essential drugs list for the proposed indication?

Experience using the product

M/OP/TC/COM will be particularly interested in the experience of USAID or any other U.S.G. agency using the drug product. The safety of a drug is initially established with premarketing clinical trials performed on a relatively small number of patients and rare, sometimes serious, adverse drug reactions may not be identified in these premarketing studies. Consequently, postmarketing data and, in particular, USAID experience of any safety problems in using a drug for the proposed application should be presented.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency (for example, CDC, U.S. Army) have any prior history or experience using the drug for the proposed application? Has the agency experienced any problems with the safety, efficacy, or quality of the product?

- Has the drug product been approved by M/OP/TC/COM for use by any other USAID Mission or CA, particularly for the proposed indication?

- Does the cooperating country have any prior history or experience using this drug for the proposed application? Has the country experienced any problems with the safety, efficacy, or quality of the product?

- Have problems with the safety, efficacy, or quality of the drug product been reported since it was first marketed?

Information on the manufacturer

It is important to select reputable manufacturers who have a history of supplying good- quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring pharmaceutical products from the manufacturer? Has the agency experienced any problems with the quality of drugs supplied?

- Does the cooperating country have any prior history or experience procuring pharmaceutical products from the manufacturer? Has the country experienced any problems with the quality of drugs supplied?

- Has the manufacturing site recently been inspected for Good Manufacturing Practice by the U.S. FDA or any other international inspection agency and/or by the resident country's regulatory/governing authority?

Request a copy of the GMP certificate or the WHO-type Certificate of Pharmaceutical Product from the manufacturer or the drug regulatory authority who issued the certificate and submit it with your application. The extent to which this certificate will assure the quality of the manufacturing facilities or processes will depend on the competency of the issuing drug regulatory authority.

- Is the manufacturer able to supply a batch certificate or certificate of analysis for the drug product that shows that it meets selected pharmacopeia or other reference standards? Include a statement that the manufacturer will be requested to provide this certificate with the invoice.

Information on the supplier (if different from the manufacturer)

It is important to select reputable suppliers and distributors who have a history of supplying good-quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring drugs from the supplier? Has the agency experienced any problems with the quality of drugs supplied?

- Does the cooperating country have any prior history or experience procuring drugs from the supplier? Has the country experienced any problems with the quality of drugs supplied?

- Have the measures that the supplier takes to assure the safety, efficacy, and quality of the drug products it supplies been evaluated by USAID or any other U.S.G. agency and found to be acceptable?

- Does the supplier routinely test the products that are supplied to ensure that the drugs meet the standards of the reference pharmacopeia?

Where to obtain information to attest to safety, efficacy, and quality of drugs

This section describes some sources from which to obtain information to attest to the safety, efficacy, and quality of drug products.

Manufacturer/supplier

You should be aware that information provided by a manufacturer may be biased in its presentation. All information provided should be evaluated carefully and supported by information from independent sources if possible. Your CTO can advise you on this subject.

The manufacturer/supplier can be contacted directly and asked to supply the following information.

- Information on valid marketing authorizations
- Certification that the drug is available for sale in the country of manufacture
- Information on special storage or operating conditions needed to maintain quality
- Information on the safety and efficacy of drug for the proposed application and problems reported since the product was first marketed
- Certificate of Good Manufacturing Practice or WHO-type Certificate of Pharmaceutical Product
- Batch certificate or certificate of analysis
- Information on testing of products by supplier (if different from manufacturer)

Cooperating country

The following information may be requested from the appropriate cooperating country MOH procurement unit, national (drug) regulatory authority, and/or national AIDS committee:

- Information and certification that the drug is registered for use in the cooperating country
- Experience using the product/supplier/manufacturer and any reported problems
- Inclusion of a drug in the cooperating country's Essential Drugs List/Formulary
- Inclusion of a drug in the cooperating country's standard treatment guidelines

WHO

Information about whether a drug is included in the WHO Essential Drugs List for the proposed application can be obtained from the WHO Web site. The WHO Essential Drugs List is available from **www.who.int/medicines/**; click on "Documents" (at the top of the page), then click on "Essential Drugs List" under "E."

CTO

Your CTO should be able to direct you to the appropriate source to provide the following information:

- Experience of other USAID Missions, departments (including BHR/OFDA), and U.S.G. agencies using drug/ manufacturer/supplier and any problems reported
- Information on whether the product has been approved by M/OP/TC/COM for use by any other USAID Mission or CA for the proposed indication
- Information on USAID (including BHR/OFDA) or any other U.S.G. agency evaluation of the supplier and measures taken by the supplier to assure safety, efficacy, and quality of products supplied

Recognized experts in field

Information on the safety and efficacy of a drug for the proposed application and reported problems since the product was first marketed can be located by consulting reputable textbooks or publications, seeking expert opinion, or conducting a literature search.

3. Pharmaceutical products other than drugs and HIV test kits

Information to attest to safety, efficacy, and quality

The following list presents examples of the kind of information that M/OP/TC/COM will expect you to submit with your application to procure non-FDA-approved pharmaceutical products other than drugs and HIV test kits such as diagnostic kits for STDs.

Regulatory information on the product

The safety and efficacy of a pharmaceutical product can usually be established if it is marketed in countries whose regulatory authorities are recognized as being effective. WHO recommendations for quality assurance include a requirement that a pharmaceutical product have a valid marketing authorization in the country in which it is produced.

- Does the pharmaceutical product have valid marketing authorization for the proposed indication in—
  - Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa?
  - The European Union or a country in the European Economic Area?
  - The country in which it is produced? Request a certificate from the manufacturer stating that the pharmaceutical product is available for sale in the country of manufacture and submit it with your request.
  - The cooperating country? Request certification from the cooperating country and submit it with your request.
- Does the pharmaceutical product require special storage or operating conditions to maintain quality?
- Does the cooperating country provide laboratory testing of the product that confirms that it meets selected pharmacopeia or other reference standards?

Expert opinion on the product

Information on safety and efficacy can also be obtained from recognized experts in the field and from reputable current publications and textbooks.

- Is the pharmaceutical product recognized as being safe and effective and recommended for the proposed application by recognized experts in the field, for example, CDC or WHO?
- Is there published data in a reputable peer-reviewed journal by recognized experts in the field available to support the safety and efficacy of the pharmaceutical product for the proposed application?

Experience using the product

M/OP/TC/COM will be particularly interested in the experience of USAID or any other U.S.G. agency using the pharmaceutical product.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency (e.g., CDC, U.S. Army) have any prior history or experience using this pharmaceutical product for the proposed application? Has the agency experienced any problems with the safety, efficacy, or quality of the product?

- Has the product been approved by M/OP/TC/COM for use by any other USAID Mission or CA, particularly for the proposed indication?

- Does the cooperating country have any prior history or experience using this pharmaceutical product for the proposed application? Has the country experienced any problems with the safety, efficacy, or quality of the product?

- Have problems with the safety, efficacy, or quality of the pharmaceutical product been reported since it was first marketed?

Information on the manufacturer

It is important to select reputable manufacturers that have a history of supplying good-quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring pharmaceutical products from the manufacturer? Has the agency experienced any problems with the quality of pharmaceutical products supplied?

- Does the cooperating country have any prior history or experience procuring pharmaceutical products from the manufacturer? Has the country experienced any problems with the quality of pharmaceutical products supplied?

- Has the manufacturing site recently been inspected for Good Manufacturing Practice by the U.S. FDA or any other international inspection agency and/or by the resident country's regulatory/governing authority?

Request a copy of the GMP certificate or the WHO-type Certificate of Pharmaceutical Product from the manufacturer or the issuing regulatory authority and submit it with your application. The extent to which this certificate will assure the quality of the manufacturing facilities or processes will depend on the competency of the issuing regulatory authority.

- Is the manufacturer able to supply a batch certificate or certificate of analysis for the product that shows that it meets selected pharmacopeia or other reference standards? Include a statement that the manufacturer will be requested to provide this certificate with the invoice.

Information on the supplier (if different from the manufacturer)

It is important to select reputable suppliers and distributors that have a history of supplying good-quality pharmaceutical products.

- Does USAID, including BHR/OFDA, or any other U.S.G. agency have any prior history or experience procuring pharmaceutical products from the supplier? Has the agency experienced any problems with the quality of pharmaceutical products supplied?

- Does the cooperating country have any prior history or experience procuring pharmaceutical products from the supplier? Has the country experienced any problems with the quality of pharmaceutical products supplied?

- Have the measures that the supplier takes to assure the safety, efficacy, and quality of the pharmaceutical products it supplies been evaluated by USAID or any other U.S.G. agency and found to be acceptable?

- Does the supplier routinely test pharmaceutical products that are supplied to ensure that the products meet the standards of the reference pharmacopeia?

Where to obtain information to attest to safety, efficacy, and quality of pharmaceutical products other than drug and HIV test kits

This section describes some sources from which to obtain information to attest to the safety, efficacy, and quality of pharmaceutical products.

Manufacturer/supplier

You should be aware that information provided by a manufacturer may be biased in its presentation, and all information provided should be evaluated carefully and supported by information from independent sources if possible. Your CTO can advise you on this subject. The manufacturer/supplier can be contacted directly and asked to supply the following information.

- Information on valid marketing authorizations
- Certification that the pharmaceutical product is available for sale in the country of manufacture
- Information on special storage or operating conditions needed to maintain quality
- Information on the safety and efficacy of a pharmaceutical product for the proposed application and problems reported since the product was first marketed
- Certificate of Good Manufacturing Practice or WHO-type Certificate of Pharmaceutical Product
- Batch certificate or certificate of analysis
- Information on testing of pharmaceutical products by supplier (if different from manufacturer)

Cooperating country

The following information may be requested from the appropriate cooperating country MOH procurement unit, national regulatory authority, and/or national AIDS committee.

- Information and certification that the pharmaceutical product is registered for use in the cooperating country
- Experience of using the product/supplier/manufacturer and any reported problems

CTO

Your CTO should be able to direct you to the appropriate source to provide the following information:

- Experience of other USAID Missions, departments (including BHR/OFDA), and U.S.G. agencies using product/manufacturer/supplier and any problems reported
- Information on whether the product has been approved by M/OP/TC/COM for use by any other USAID Mission or CA for the proposed indication
- Information on USAID (including BHR/OFDA) or any other U.S.G. agency's evaluation of the supplier, and measures taken by the supplier to assure safety, efficacy, and quality of products supplied

Recognized experts in field

Information on the safety and efficacy of the pharmaceutical product for the proposed application and reported problems since the product was first marketed can be located by consulting reputable textbooks or publications, seeking expert opinion, or conducting a literature search.

Section F

Appropriateness of the product for the proposed application and the program context

In order to approve your request to procure a pharmaceutical product, M/OP must be satisfied that the pharmaceutical product, whether FDA approved or not, is appropriate for the proposed application in the specific context in which it will be used. In addition, if you can build a compelling argument that the available U.S. source and/or U.S. origin and/or FDA-approved products are inappropriate for the proposed application and/or the program context, this information will support your request for approval to procure a non–U.S. source and/or non–U.S. origin and/or non-FDA-approved product in preference.

Section F describes the kind of issues that M/OP will expect you to consider and suggests some possible sources of information. Consult your CTO for further guidance.

Contents of Section F

1. Issues to consider regarding appropriateness for the proposed application and program context

M/OP will expect you to consider the following issues in your request for approval to procure pharmaceutical products. This list may not be comprehensive; please consult your CTO for further guidance.

- Are the environmental conditions under which the product is to be stored or used appropriate?
  - Does the pharmaceutical product require refrigeration during storage? Are refrigerators available to store the product? M/OP will expect you to provide information on the refrigeration and monitoring procedures that will be implemented to assure the quality and effectiveness of the equipment.
  - Will the performance or efficacy of the pharmaceutical product be compromised at the temperature of the normal operating conditions in which it is to be used?
- Is the pharmaceutical product compatible with cooperating country essential drugs list/formulary/ standard treatment guidelines and/or HIV testing guidelines/algorithm?
- Is the pharmaceutical product licensed for use in the cooperating country?
- Will procurement of the pharmaceutical product harmonize with other donations?
- Is the pharmaceutical product appropriate for the local context in which it is to be used?
  - Is the language of the instructions appropriate to the local situation? Will expense be incurred in translating instructions?
  - Are the technical or medical staff trained or experienced in using the pharmaceutical product? Will expense be incurred with retraining?
  - Specifically with respect to HIV test kits, will the product detect the HIV variants present in the community in which it is to be used, for example HIV-2, or subgroups, for example HIV-1-O?

- Is the pharmaceutical product appropriate for the local technical capacity?
  - Is the technical expertise available to use the product correctly? Are laboratory staff available who are trained and experienced in using complex HIV tests such as ELISA, Western blot, or even simple/rapid HIV tests graded as moderately complex?
  - Is additional equipment available that is essential to use the product correctly? For example, is a centrifuge available for separating serum and plasma from whole blood for HIV test kits that test serum/plasma and, also, is electricity available to operate the centrifuge? M/OP will expect you to provide information and assurances on the quality and effectiveness of essential supporting equipment.
- Do the characteristics of the pharmaceutical product compromise the objectives of the program?
  - A diagnostic test kit that requires several days to produce a result is inappropriate for a program aiming to provide same-day testing.
  - Do you plan to expand your program and, if so, will the product be appropriate for the expanded program?

Documentation

Documentation should be provided to support your justification and may include—

- Copies of relevant sections of cooperating country guidelines/testing algorithms, standard treatment guidelines, and/or essential drugs list/formulary
- A statement from a cooperating country official that the pharmaceutical product has been evaluated for the local context in which it is to be used or that it is the approved product for the proposed application and that local staff are trained and experienced in using the product

2. Sources of information

Cooperating country

Contact cooperating country officials for information on formularies, essential drug lists, testing algorithms/ guidelines, local technical capacity, and appropriateness of the product for the local context as well as to coordinate harmonization of donations.

Manufacturer

Consult the manufacturer's product information or Web site, or contact the manufacturer directly. The contact information for manufacturers of selected HIV test kits is listed in Annex 11.

CTO

Consult your CTO for information on other USAID Missions and/or CAs that have prepared applications for similar products that have been approved that may be able to provide you with assistance.

CDC

If the country has an HIV testing algorithm/guidelines, contact CDC and/or the officials who were involved in designing and evaluating the testing algorithm at country level. They should be able to provide you with information on how and why the kits were selected. Contact information for CDC is listed in Annex 12.

"Rapid Tests for HIV Antibody" prepared by Dr. Bernard M. Branson from CDC summarizes data on the characteristics and performance of rapid HIV tests from peer-reviewed journals and conference abstracts. Data from test manufacturers are not included unless corroborated by independent evaluations. This article is available from *AIDS Reviews 2000*, 2: 76–83, and is also currently on the Web site **http://www.medadvocates.org/cdc/rapidtest.html** [accessed December 20, 2001].

WHO

WHO periodically evaluates ELISAs and simple/rapid HIV test kits that are available for bulk purchase by the public sector. Results of these evaluations are available in Comparative Evaluation of the Operational Characteristics of Commercially Available Assays to Detect Antibodies to HIV-1 and/or HIV-2 in Human Sera at **http://www.who.int/pht/blood_safety/hivkits.html** [accessed December 20, 2001].

Section G

Information to attest that the product will be used safely, effectively, and appropriately in the program

Section G refers to the requirement to satisfy M/OP that the product will be used safely, effectively, and appropriately in your program and consequently is project-specific. The CTO for your project will provide specific information on what you will need to provide and advise you on where to get the information.

Section G describes some issues that have been identified in previous requests for approval to procure pharmaceutical products.

- Following are some issues that have been identified in previous requests.
  - Are protocols available for the use of the product?
  - What is the staff's experience and qualifications to manage, use, and administer the pharmaceutical product safely and effectively?
  - What systems are in place to monitor and evaluate the program?
  - How do the objectives of the program fit in with the objectives at district, regional, and country level?
  - Does the infrastructure exist to maintain the quality of the pharmaceutical products from the time of receipt through storage, distribution, and use?
- Some specific concerns that have been identified in previous requests for HIV test kits include the following.
  - Verify that you have team members that are experienced in the very sensitive issues related to HIV VCT.

- Specify how you will address—
  - Confidentiality
  - Record keeping
  - Outreach to partners
  - Cultural social values for HIV-positive women, including pressure to breast-feed
  - Care and support for HIV-positive clients

- Verify that an internal quality assurance program will be instituted to monitor the performance of the HIV testing algorithm/guidelines.

Annexes

Annex I
Summary of USAID Regulations and Policies Relevant to Procurement of Pharmaceutical Products

Summary of USAID Regulations and Policies Relevant to Procurement of Pharmaceutical Products

1. Objectives of USAID Policies and Procedures

ADS 312 Eligibility of Commodities contains USAID's policies and essential procedures for pharmaceutical procurement. The objectives of these policies and procedures are stated in ADS 312.2 as follows:

1. To assure that the resources made available by USAID in the form of commodities make a positive contribution to development.

2. To assure that USAID programs are implemented in full accord with the Foreign Assistance Act, other pertinent laws, and relevant U.S. policies.

3. To assure that only safe and efficacious pharmaceutical products are financed, that they are manufactured in accordance with accepted quality standards, that prices paid for them are appropriate, and that in all respects, USAID's financing of pharmaceutical procurements is carried out in a manner sensitive to the special public and Congressional interests in this important commodity.

4. To provide for economical procurement of contraceptive products.

2. Pharmaceutical Procurement Policies and Procedures

USAID's policies for procurement of pharmaceutical products are detailed in ADS 312.5.3c Pharmaceuticals.

The following policies apply to pharmaceuticals.

1) Approval Requirement – To be eligible for USAID financing, all pharmaceutical and biological products, including oral rehydration salts, must comply with U.S. Food and Drug Administration (or other controlling U.S. authority) regulations governing United States interstate shipping of such products unless the M/OP/COM approves the procurement of the product prior to financing. The following types of pharmaceuticals and biological products, which do not meet this requirement, must be approved by M/OP/COM prior to financing:

a. Prescription pharmaceuticals which are not FDA-approved products;

b. Nonprescription pharmaceuticals which are not FDA-approved products or covered by a final over-the-counter drug monograph; and

c. Biological products which are not FDA-approved products from an FDA-approved establishment.

2) Source/Origin Requirement – The source and origin of USAID-financed pharmaceuticals is limited to the United States. **(See E312.5.3c, para. 2) for exceptions)**

3) Patent Infringement – The procurement of pharmaceuticals outside the United States which infringe on U.S. patents is prohibited.

4) Generic description – All pharmaceuticals must be generically described in the solicitation document unless they are being purchased for resale under a CIP.[1] Under CIPs, when the procurement is undertaken by public or private sector entities purchasing for resale, where brand name acceptance is an important factor, brand name procurement is allowable.

5) Price Rules- CIPS – In addition to the applicable price rules in Subpart G of 22 CFR 201 (AID Regulation 1) **(See Mandatory Reference, 22 CFR 201, Subpart G)**, bulk pharmaceuticals are subject, at the pre-financing stage, to the special price rules found in Part II-D of the "USAID Commodity Eligibility Listing" **(See Mandatory Reference, USAID Commodity Eligibility Listing)**.

USAID's essential procedures for the procurement of pharmaceutical products are detailed in ADS E312.5.3c Pharmaceuticals.

The following essential procedures must be followed when dealing with pharmaceuticals.

1) Approval Requirement - Submissions of proposed pharmaceutical procurements for approval by M/OP/COM must include the generic name, dosage form, strength or concentration, unit package size, the intended therapeutic use, name of the manufacturer, and any other relevant factors bearing upon a specific application.

…

[1] CIP - Commodity Import Program

3. Exceptions to U.S. Source/Origin Rule

As stated above in ADS 312.5.3c, paragraph 2, the source and origin of USAID-financed pharmaceuticals are limited to the United States. The criteria under which exceptions to this U.S. source and origin rule can be made are set out in ADS E312.5.3c, paragraph 2, and 22 CFR Part 228, Subpart F. The criteria stated in both sections must be fulfilled.

ADS E312.5.3c Pharmaceuticals

The following essential procedures must be followed when dealing with pharmaceuticals.
…

2) Source/Origin Requirement

Exceptions to the general rule that USAID-financed pharmaceuticals must be of U.S. source and origin shall be made in accordance with the requirements in Subpart F of 22 CFR 228 (AID Regulation 28), after clearance by the Office of Procurement (M/OP/COM) **(See Mandatory Reference, 22 CFR Part 228, Subpart F).** However, if the USAID Geographic Code 941[2] is the authorized source for procurement under the assistance agreement, an exception from the U.S. source requirement to permit a specific pharmaceutical procurement from a code 941 country requires only the approval of the Office of Procurement
(M/OP/COM).

a. Under assistance other than CIPs,[3] a waiver of the U.S. source policy will be considered if:

1. The pharmaceutical product is essential to the activity.

2. The product, in the same or substantially equivalent, is not available from the United States, or the delivered price from the United States would be at least 50 percent more than from another source; and

3. Information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.

b. Under CIPs, the waiver to the U.S. source policy will be considered if:

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[2] See Annex 4 for geographic codes.

[3] CIP - Commodity Import Program

1. The pharmaceutical product is essential to the activity.

2. The product, in the same or substantially equivalent form, is not available from the United States; and

3. The product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.

3) Patent Infringement – USAID must obtain express authorization of the owner of the patent before it finances a pharmaceutical product manufactured outside of the United States which would involve use of, or be covered by, an unexpired patent of the United States which has not previously been held invalid by an unappealed or unappealable judgement or decree of a court of competent jurisdiction. This requirement cannot be waived.

22 CFR Part 228, Subpart F

Exceptions made to the rule that USAID-financed pharmaceuticals be of U.S. source and origin must also be in accordance with the requirements for commodities set out in Subpart F of 22 CFR 228 Section 228.51, of which the following are relevant to pharmaceutical products:

(a) Waiver criteria. Any waiver must be based upon one of the criteria listed in this section. Waivers to Geographic Code 899 or Code 935 which are justified under paragraph (a)(2) or (3) of this section may only be authorized on a case-by-case basis. A waiver may be authorized when:

(1) A commodity required for assistance is of a type that is not produced in or available for purchase in the United States; in addition, for waivers to any country or Geographic code beyond Code 941 and the cooperating country, the commodity is of a type that is not produced in or available for purchase in any country in Code 941 or the cooperating country.

(2) It is necessary to permit procurement in a country not otherwise eligible in order to meet unforeseen circumstances, such as emergency situations.

(3) It is necessary to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(4) For waivers to authorize procurement from Geographic

Code 941 or the cooperating country:

(i) For assistance other than commodity import programs, when the lowest available delivered price from the United States is reasonably estimated to be 50 percent or more higher than the delivered price from a country or area included in Geographic Code 941 or the cooperating country.

(ii) …

(c) Any individual transaction not exceeding $5,000 (not including transportation) does not require a waiver. In no event, however, shall procurement be from a non-Code 935 source. **[M/OP/TC/COM advises that this exemption does not apply to restricted commodities including pharmaceutical products.]**

Annex 2
ADS 312 Eligibility of Commodities

Major Functional Series 300: Acquisition & Agreement
ADS 312 ELIGIBILITY OF COMMODITIES

312.1 Authority
312.2 Objective
312.3 Responsibility
312.4 Definitions
312.5 POLICY
312.5.1 "AID COMMODITY ELIGIBILITY LISTING"
E312.5.1 "AID Commodity Eligibility Listing" - N/A
312.5.1a COMMODITY IMPORT PROGRAMS
E312.5.1a Commodity Import Programs
312.5.1b OTHER ACTIVITIES
E312.5.1b Other Activities - N/A
312.5.2 PRIOR APPROVAL OF COMMODITY TRANSACTIONS
E312.5.2 Prior Approval of Commodity Transactions
312.5.3 RESTRICTED COMMODITIES
E312.5.3 Restricted Commodities
312.5.3a AGRICULTURAL COMMODITIES
E312.5.3a Agricultural Commodities
312.5.3b MOTOR VEHICLES
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312.5.3c PHARMACEUTICALS
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312.5.3d CONTRACEPTIVES
E312.5.3d Contraceptives
312.5.3e PESTICIDES
E312.5.3e Pesticides
312.5.3f USED EQUIPMENT
E312.5.3f Used Equipment
312.5.3g FERTILIZER
E312.5.3g Fertilizer - N/A
312.5.4 INELIGIBLE COMMODITIES
E312.5.4 Ineligible Commodities - N/A
312.5.4a MILITARY EQUIPMENT
E312.5.4a Military Equipment - N/A
312.5.4b SURVEILLANCE EQUIPMENT
E312.5.4b Surveillance Equipment - N/A
312.5.4c COMMODITIES AND SERVICES FOR SUPPORT OF POLICE AND OTHER LAW ENFORCEMENT ACTIVITIES
E312.5.4c Commodities and Services for Support of Police and Other Law Enforcement Activities - N/A
312.5.4d ABORTION EQUIPMENT AND SERVICES
E312.5.4d Abortion Equipment and Services - N/A
312.5.4e LUXURY GOODS
E312.5.4e Luxury Goods - N/A

312.5.4f	GAMBLING EQUIPMENT
E312.5.4f	Gambling Equipment - N/A
312.5.4g	WEATHER MODIFICATION EQUIPMENT
E312.5.4g	Weather Modification Equipment - N/A
312.5.5	ELIGIBILITY OF COMMODITIES DETERMINED BY INELIGIBILITY OF THE CARRIER
E312.5.5	Eligibility of Commodities Determined by Ineligibility of the Carrier – N/A
312.5.5a	EFFECTS OF CARRIER INELIGIBILITY
E312.5.5a	Effects of Carrier Ineligibility - N/A
312.5.5b	WAIVERS
E312.5.5b	Waivers - N/A
312.5.6	ELIGIBILITY OF COMMODITIES DETERMINED BY INELIGIBILITY OF MARINE INSURANCE
E312.5.6	Eligibility of Commodities Determined by Ineligibility of Marine Insurance - N/A
312.6	Supplementary Reference - N/A
312.7	Mandatory Reference

Major Functional Series 300: Acquisition & Agreement

ADS 312 ELIGIBILITY OF COMMODITIES

312.1 Authority

1. Foreign Assistance Act of 1961, as amended, (FAA) Sections 102, 104(f), 604, 606(c), 607, 636(i) and 660.
2. Section 525 of the Foreign Assistance and Related Program Appropriations Act, 1982.
3. 22 CFR 216

312.2 Objective

1. To assure that the resources made available by USAID in the form of commodities make a positive contribution to development.

2. To assure that USAID programs are implemented in full accord with the Foreign Assistance Act, other pertinent laws, and relevant U.S. policies.

3. To assure that only safe and efficacious pharmaceutical products are financed, that they are manufactured in accordance with accepted quality standards, that prices paid for them are appropriate, and that in all respects, USAID's financing of pharmaceutical procurements is carried out in a manner sensitive to the special public and Congressional interests in this important commodity.

4. To provide for economical procurement of contraceptive products.

*** 5. This Chapter covers the policies on the eligibility of commodities for financing with program funds. It does not deal with programmatic determinations of commodity eligibility. The policy on motor vehicles also applies to Operating Expense funds.**

…

312.5.3c PHARMACEUTICALS

The following policies apply to pharmaceuticals.

1) Approval Requirement - To be eligible for USAID financing, all pharmaceutical and biological products, including oral rehydration salts, must comply with the U.S. Food and Drug Administration (or other controlling U.S. authority) regulations governing United States interstate shipment of such products unless the M/OP/COM approves the procurement of the product prior to financing. The following types of pharmaceuticals and biological products, which do not meet this requirement, must be approved by M/OP/COM prior to financing:

a. Prescription pharmaceuticals which are not FDA-approved products**;**

b. Nonprescription pharmaceuticals which are not FDA-approved products or covered by a final over-the-counter drug monograph; and

c. Biological products which are not FDA-approved products from an FDA-approved establishment.

2) Source/Origin Requirement - The source and origin of USAID-financed pharmaceuticals is limited to the United States. **(See E312.5.3c, para. 2) for exceptions)**

3) Patent Infringement - The procurement of pharmaceuticals outside the United States which infringe on U.S. patents is prohibited.

4) Generic Description - All pharmaceuticals must be generically described in the solicitation document unless they are being purchased for resale under a CIP. Under CIPs, when the procurement is undertaken by public or private sector entities purchasing for resale, where brand name acceptance is an important factor, brand name procurement is allowable.

5) Price Rules - CIPS - In addition to the applicable price rules in Subpart G of 22 CFR 201 (AID Regulation 1)**(See Mandatory Reference, 22 CFR 201, Subpart G)**, bulk pharmaceuticals are subject, at the pre-financing stage, to the special price rules found in Part II-D of the "USAID Commodity Eligibility Listing" **(See Mandatory Reference, USAID Commodity Eligibility Listing)**.

E312.5.3c Pharmaceuticals

The following essential procedures must be followed when dealing with pharmaceuticals.

1) Approval Requirement - Submissions of proposed pharmaceutical procurements for approval by M/OP/COM must include the generic name, dosage form, strength or concentration, unit

package size, the intended therapeutic use, name of the manufacturer, and any other relevant factors bearing upon a specific application.

2) Source/Origin Requirement

Exceptions to the general rule that USAID-financed pharmaceuticals must be of U.S. source and origin shall be made in accordance with the requirements in Subpart F of 22 CFR 228 (AID Regulation 28), after clearance by the Office of Procurement (M/OP/COM)**(See Mandatory Reference, 22 CFR Part 228, Subpart F)**. However, if the USAID Geographic Code 941 is the authorized source for procurement under the assistance agreement, an exception from the U.S. source requirement to permit a specific pharmaceutical procurement from a code 941 country requires only the approval of the Office of Procurement (M/OP/COM).

a. Under assistance other than CIPs, a waiver of the U.S. source policy will be considered if:

1. The pharmaceutical product is essential to the activity;

2. The product, in the same or substantially equivalent form, is not available from the United States, or the delivered price from the United States would be at least 50 percent more than from another source; and

3. Information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.

b. Under CIPs, waiver of the U.S. source policy will be considered if:

1. The pharmaceutical product is essential;

2. The product, in the same or substantially equivalent form, is not available from the United States; and

3. The product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.

3) Patent Infringement - USAID must obtain express authorization of the owner of the patent before it finances a pharmaceutical product manufactured outside the United States which would involve use of, or be covered by, an unexpired patent of the United States which has not previously been held invalid by an unappealed or unappealable judgment or decree of a court of competent jurisdiction. This requirement cannot be waived.

312.5.3d CONTRACEPTIVES

The following policies apply to procurement of contraceptive products.

1) Consolidated Contracts - Unless otherwise authorized by the Office of Population, contraceptives and related supplies shall be procured under contracts which are managed by Bureau for Global Programs, Field Support and Research, Center for Population, Health, and Nutrition, Office of Population, (G/PHN/POP). The same specifications shall be used for all USAID-funded program requirements. All condoms provided for HIV/AIDS programs shall also be procured under the centrally managed contraceptives contracts. Products which are currently available under centrally managed contracts are: condoms, oral contraceptive pills, IUDs, injectables, sub-dermal implants, and vaginal foaming tablets.

2) Source/Origin and Nationality - Contraceptive products shall meet the requirements for U.S. source, origin and nationality in Subpart B of 22 CFR 228 (AID Regulation 28) **(See Mandatory Reference, 22 CFR 228, Subpart B)** unless a waiver is approved in accordance with Subpart F of 22 CFR 228 (AID Regulation 28) **(See Mandatory Reference, 22 CFR Part 228, Subpart F)**.

3) USAID Emblems - USAID emblems are not required for shipments of contraceptives and related supplies to activities operated by USAID recipient organizations. Missions may also specify in their procurement requests that USAID emblems not be required.

E312.5.3d Contraceptives

The following essential procedures must be followed when dealing with pharmaceuticals.

1) Consolidated Contracts

a. Missions and contractors or recipients whose programs require contraceptive supplies shall provide estimates of needs to G/POP. These estimates may be updated at any time and shall include product needs for up to two future calendar years.

b. The funding required for contraceptive procurements shall normally be provided by Missions through designating and authorizing the use of Operating Year Budget funds by G/POP. In some cases Missions may make previously obligated funds available; in these cases, the obligating agreement shall permit use of the funds in any of the contraceptive contracts designated by G/POP and disbursement by USAID/W.

c. G/POP shall aggregate the quantities of each product that is required and shall request the Office of Procurement to secure the needed products and related freight forwarding services through annual contracts.

2) Source/Origin and Nationality - Waiver of this requirement shall be initiated or cleared by G/POP.

Annex 3
22 Code of Federal Regulations (CFR) Part 228

PART 228—RULES ON SOURCE, ORIGIN AND NATIONALITY FOR COMMODITIES AND SERVICES FINANCED BY USAID

Subpart A—Definitions and Scope of This Part

Subpart B—Conditions Governing Source and Nationality of Commodity Procurement Transactions for USAID Financing

Subpart C—Conditions Governing the Eligibility of Commodity-Related Services for USAID Financing

Subpart D—Conditions Governing the Nationality of Suppliers of Services for USAID Financing

Subpart E—Conditions Governing Source and Nationality of Local Procurement Transactions for USAID Financing

Subpart F—Waivers

AUTHORITY: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended, E.O. 12163, Sept. 29, 1979, 44 FR 56673: 3 CFR 1979 Comp., p. 435.

SOURCE: 61 FR 53616, Oct. 15, 1996, unless otherwise noted.

Subpart A—Definitions and Scope of This Part

§ 228.01 Definitions.

As used in this part, the following terms shall have the following meanings:

(a) *Commodity* means any material, article, supply, goods, or equipment.

(b) *Commodity-related services* means delivery services and/or incidental services.

(c) *Component* means any good that goes directly into the production of a produced commodity.

(d) *Cooperating country* means the country receiving the USAID assistance subject to this part 228.

(e) *Delivery* means the transfer to, or for the account of, an importer of the right to possession of a commodity, or, with respect to a commodity-related service, the rendering to, or for the account of, an importer of any such service.

(f) *Delivery service* means any service customarily performed in a commercial export transaction which is necessary to effect a physical transfer of commodities to the cooperating country. Examples of such services are the following: export packing, local drayage in the source country (including waiting time at the dock), ocean and other freight, loading, heavy lift, wharfage, tollage, switching, dumping and trimming, lighterage, insurance, commodity inspection services, and services of a freight forwarder. "Delivery services" may also include work and materials necessary to meet USAID marking requirements.

(g) *Implementing document* means any document, such as a contract, grant,

letter of commitment, etc., issued by USAID which authorizes the use of USAID funds for the procurement of services or commodities and/or commodity related services, and which specifies conditions which apply to such procurement.

(h) *Incidental services* means the installation or erection of USAID-financed equipment, or the training of personnel in the maintenance, operation and use of such equipment.

(i) *Mission* means the USAID Mission or representative in a cooperating country.

(j) *Origin* means the country where a commodity is mined, grown or produced. A commodity is produced when, through manufacturing, processing, or substantial and major assembling of components, a commercially recognized new commodity results that is significantly different in basic characteristics or in purpose of utility from its components.

(k) *Services* means the performance of identifiable tasks, rather than the delivery of an end item of supply.

(l) *Source* means the country from which a commodity is shipped to the cooperating country, or the cooperating country if the commodity is located therein at the time of the purchase. Where, however, a commodity is shipped from a free port or bonded warehouse in the form in which received therein, "source" means the country from which the commodity was shipped to the free port or bonded warehouse.

(m) *State* means the District of Columbia or any State, commonwealth, territory or possession of the United States.

(n) *Supplier* means any person or organization, governmental or otherwise, who furnishes services, commodities and/or commodity related services financed by USAID.

(o) *United States* means the United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S. associated sovereignty, including commonwealths, territories and possessions.

(p) *USAID* means the U.S. Agency for International Development or any successor agency, including when applicable, each USAID Mission abroad.

(q) *USAID Geographic Code* means a code in the USAID Geographic Code Book which designates a country, a group of countries, or an otherwise defined area. The principal USAID geographic codes are described in § 228.03.

(r) *USAID/W* means the USAID in Washington, DC 20523, including any office thereof.

§ 228.02 Scope and application.

This part is applicable to goods and services financed directly with program funds under the Foreign Assistance Act of 1961, as amended, unless otherwise provided by statute or regulation. If different conditions apply to a USAID-financed procurement, by statute or regulation, those conditions shall be incorporated in the implementing document and shall prevail in the event of any conflict with this part 228. The implementing documents will indicate the authorized source of procurement. The terms and conditions applicable to a procurement of goods or services shall be those in effect on the date of the issuance of a contract for goods or services by USAID or by the cooperating country.

§ 228.03 Identification of principal geographic code numbers.

The USAID Geographic Code Book sets forth the official description of all geographic codes used by USAID in authorizing or implementing documents, to designate authorized source countries or areas. The following are summaries of the principal codes:

(a) Code 000—*The United States:* The United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S.-associated sovereignty, including commonwealths, territories and possessions.

(b) Code 899—Any area or country, except the cooperating country itself and the following foreign policy restricted countries: Afghanistan, Libya, Vietnam, Cuba, Cambodia, Laos, Iraq, Iran, North Korea, Syria and People's Republic of China.

(c) Code 935—Any area or country including the cooperating country, but excluding the foreign policy restricted countries.

(d) Code 941—The United States and any independent country (excluding

foreign policy restricted countries), except the cooperating country itself and the following: Albania, Andorra, Angola, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Belarus, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia,* Malta, Moldova, Monaco, Mongolia, Montenegro,* Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, San Marino, Saudi Arabia, Serbia,* Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan,* Tajikistan, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, and Vatican City.

[61 FR 53616, Oct. 15, 1996; 61 FR 54849, Oct. 22, 1996]

[Additional material purposely omitted.]

* Has the status of a "Geopolitical Entity", rather than an independent country.

(f) The following commodities and services which are only available locally:

(1) Utilities, including fuel for heating and cooking, waste disposal and trash collection;

(2) Communications—telephone, telex, facsimile, postal and courier services;

(3) Rental costs for housing and office space;

(4) Petroleum, oils and lubricants for operating vehicles and equipment;

(5) Newspapers, periodicals and books published in the cooperating country;

(6) Other commodities and services (and related expenses) that, by their nature or as a practical matter, can only be acquired, performed, or incurred in the cooperating country, e.g., vehicle maintenance, hotel accommodations, etc.

Subpart F—Waivers

§ 228.50 General.

USAID may expand the authorized source in order to accomplish project or program objectives by processing a waiver. When a waiver is processed to include a new country, area, or geographic code, procurement is not limited to the added source(s), but may be from any country included in the authorized geographic code. All waivers must be in writing.

§ 228.51 Commodities.

(a) *Waiver criteria.* Any waiver must be based upon one of the criteria listed in this section. Waivers to Geographic Code 899 or Code 935 which are justified under paragraph (a)(2) or (3) of this section may only be authorized on a case-by-case basis. A waiver may be authorized when:

(1) A commodity required for assistance is of a type that is not produced in or available for purchase in the United States; in addition, for waivers to any country or Geographic code beyond Code 941 and the cooperating country, the commodity is of a type that is not produced in or available for purchase in any country in Code 941 or the cooperating country.

(2) It is necessary to permit procurement in a country not otherwise eligible in order to meet unforeseen circumstances, such as emergency situations.

(3) It is necessary to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(4) For waivers to authorize procurement from Geographic Code 941 or the cooperating country:

(i) For assistance other than commodity import programs, when the lowest available delivered price from the United States is reasonably estimated to be 50 percent or more higher than the delivered price from a country or area included in Geographic Code 941 or the cooperating country.

(ii) For assistance other than commodity import programs, when the estimated cost of U.S. construction materials (including transportation and handling charges) is at least 50 percent higher than the cost of locally produced materials.

(iii) For commodity import programs or similar sector assistance, an acute shortage exists in the United States for a commodity generally available elsewhere.

(iv) Persuasive political considerations.

(v) Procurement in the cooperating country would best promote the objectives of the foreign assistance program.

(vi) Such other circumstances as are determined to be critical to the success of project objectives.

(b) *Additional requirements.* A waiver to authorize procurement from outside the United States of agricultural commodities, motor vehicles, or pharmaceuticals (see § 228.13, "Special source rules requiring procurement from the United States,") must also meet requirements established in USAID directives on commodity eligibility. (USAID's Automated Directives System Chapter 312.)

(c) Any individual transaction not exceeding $5,000 (not including transportation) does not require a waiver. In no event, however, shall procurement be from a non-Code 935 source.

[61 FR 53616, Oct. 15, 1996; 62 FR 314, Jan. 3, 1997, as amended at 63 FR 38751, July 20, 1998]

Annex 4
USAID Geographic Codes

USAID Geographic Code	Description
Code 000 – The United States	The United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S.-associated sovereignty, including commonwealths, territories, and possessions.
Code 899 – Free World	Any area or country, except the cooperating country itself and the following foreign policy restricted countries: Afghanistan, Libya, Vietnam, Cuba, Cambodia, Laos, Iraq, Iran, North Korea, Syria, and the People's Republic of China.
Code 935 – Special Free World	Any area or country in the Free World including the cooperating country, but excluding the foreign policy restricted countries.
Code 941 – Selected Free World	The United States and any independent country in the Free World (excluding foreign policy restricted countries), except the cooperating country itself and the following: Albania, Andorra, Angola, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Belarus, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia,* Malta, Moldova, Monaco, Mongolia, Montenegro,* Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, San Marino, Saudi Arabia, Serbia,* Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan,* Tajikistan, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, and Vatican City. * Has the status of "Geopolitical Entity" rather than independent country.

Annex 5
Source/Origin Waiver for Selected Pharmaceuticals for STDs and OIs

Source/Origin Waiver
Selected Pharmaceuticals for STDs and OIs

PROBLEM

Approval is requested for a waiver of FAA Section 604 from Geographic Code 000 (U.S) to Geographic Code 935 (Special Free World) to allow the procurement of selected STD pharmaceuticals for the treatment of sexually transmitted diseases (STD) and specific opportunistic infections (OI). This request is to allow Geographic Code 935 to be an authorized source/origin for pharmaceuticals for the HIV/AIDS Results Package. All specific requests for Code 935 procurement of STD pharmaceuticals will be submitted to M/OP/COMS for review and approval prior to initiating the procurement.

DISCUSSION

There has been a continuing problem with the procurement of pharmaceuticals for the treatment of STDs and OIs in HIV/AIDS programs due to the FAA Section 604 general U.S. source/origin requirement and specific Agency policy that all pharmaceuticals financed by USAID must be of U.S source and origin. The problem is due primarily to two factors, the high cost of U.S pharmaceuticals and incompatibility with host country national formularies.

A major consideration in the development of STD components of USAID financed HIV/AIDS programs is the design of activities that will be sustainable over the long term. The costs and types of STD drugs selected for these programs play a major role in determining whether the host country will have a sustainable STD effort or not. Without appropriate and cost effective drugs these STD components will not be sustainable. A price comparison of STD drugs using GSA prices for U.S. pharmaceuticals versus the same drugs available through UNICEF from Code 935 countries reveals that most U.S. STD pharmaceuticals are from 50 percent to more than 900 percent more expensive than the comparable drug available from UNICEF. Given such a price difference and the fact that in general host country budgets for drugs are chronically underfunded, it would not be cost effective to insist on the procurement of U.S pharmaceuticals for USAID financed STD components of HIV/AIDS programs when lower cost and equal quality drugs are available from Code 935 suppliers such as UNICEF.

A similar problem exists regarding the incompatibility of U.S. pharmaceuticals with the national formularies and essential drug lists of many of the developing countries in which we work. In many developing countries, drug procurement policies restrict purchases to only those medications included on national formularies or country essential drug lists and often U.S pharmaceuticals are not on these lists. This means that U.S pharmaceuticals generally are not available in host country health programs and therefore personnel are not familiar

with them. In addition, many of the brand specific drugs included on these lists are not available in the U.S. While it might be possible to get a U.S. pharmaceutical on a particular developing country drug list, especially a generic formulation, there is little likelihood it would be used due to personnel not being familiar with it or not trained regarding its use. The fact that it might be a U.S. generic formulation does not solve the problem since often there may be slight variations in formulations from other Code 935 country drugs with which host country health personnel are more familiar. Insisting on the use of U.S. pharmaceuticals in USAID financed HIV/AIDS programs would introduce an element that would last only as long as USAID financing lasted and would result in a less sustainable and significantly more costly program.

USAID pharmaceutical policy is addressed in ADS section 312.5.3c(2) which notes that pharmaceuticals used in USAID financed programs must be manufactured in the United States. 22 CFR 228 indicates that waivers of this requirement to allow geographic code 935 procurement are possible if the procurement meets one of the following criteria: 1) the commodity is not produced or available in the U.S. 2) it is necessary to permit procurement in a country not otherwise eligible due to some unforeseen or emergency circumstance or 3) the procurement is necessary to promote efficiency in the use of U.S foreign assistance resources. Clearly, criteria 1 and 3 would be relevant to this particular waiver request.

In addition to the above general criteria, ADS Section E312.5.3c(2) notes that any waiver allowing non U.S. procurement for pharmaceuticals also must meet ADS Section 310.5.4. special requirements. This chapter of the ADS restates the U.S source/origin requirement for USAID financed pharmaceuticals but indicates that non U.S. procurement of pharmaceuticals can be considered provided that the procurement is approved by M/OP/COMS and meets the following criteria: 1) the pharmaceutical is essential to the activity; 2) the product, in the same or substantially equivalent form, is not available from the United States, or the delivered price would be at least 50 percent more than from another source; or 3) information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority. In addition, ADS Section E312.5.3c(3) requires that any non U.S. pharmaceutical product procured may not violate U.S Patent laws. All pharmaceuticals proposed for Code 935 procurement under the HIV/AIDS Results Package will conform to ADS Chapters 310 and 312 and 22 CFR 228 requirements.

Recommendation: That, by approving this HIV/AIDS Results Package, the Deputy Assistant Administrator for the Center for Population Health and Nutrition waive FAA Section 604 requirements and approve Geographic Code 935 as the authorized source/origin for the procurement of pharmaceuticals for the treatment of sexually transmitted diseases and selected opportunistic infections for the HIV/AIDS Results Package. For all other commodities financed under this Results Package, Geographic Code 000, unless waived on a case by case basis, is the authorized source/origin. All requests for Code 935 procurement of HIV/STD pharmaceuticals must be reviewed and approved by M/OP/COMS prior to initiating any procurement.

APPROVED _____

DATE 12.15.1997

Clearance:
GC/G:CKarr (Draft)
M/OP/A/HRN:EAtsalinos NOV 26 1997
M/OP/COMS _____
Other Clearances: As shown on the Action Memorandum

Annex

Illustrative STD/OI Drug List

Metronidiazole Tablet, 250mg
Metronidiazole Tablet, 500mg
Erythromycin Stearate Tablet, 250mg
Ampicillin Trihydrate Caps, 500mg
Probenecid Tablet, 500mg
Gentamicin Sulfate Injection, eq 40mg base/ml
Sulfamethazole Trimethoprim Tablet, 400mg, 80mg
Doxycycline Hyclate Tablet, 100mg
Tetracycline HCL Capsule, 500mg
Sterile Water for Injection
Kanamycin Sulfate Injection, eq 1GM base/3ml vial
Nystatin Vaginal Tablet, 100,000 units w/applicator
Amoxicillin Capsule, 250mg
Cipofloxacin HCL Tablet, 500mg
Cefixime Tablet, 200mg
Cefixime Tablet, 400mg
Spectinomycin HCL Injection, eq 2GM base/vial + diluent
Azithromycin Capsule, 250mg
Amoxicillin Clavulanate Potassium Tablet, 250mg eq 125mg Acid
Ciprofloxacin HCL Tablet, 500mg
Penicillin Benzathine Benzyl 2.4 MU Powder

Annex 6
Source/Origin Waiver for HIV Test Kits

[Approved by J. Brady Anderson, USAID Administrator, on January 11, 2001, and effective from this date.]

January 11, 2001

ACTION MEMORANDUM

TO: The Administrator

FROM: A-AA/G Barbara Turner /s/

SUBJECT: The HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits)

ISSUE FOR DECISION

Whether to authorize the procurement of testing kits from Code 935 countries (any country or area excluding foreign policy restricted countries).

ESSENTIAL FACTORS

In a December 19, 2000, Action Memorandum (See Tab 2) you approved certain waivers and expedited procedures to acquire services and commodities for the Agency's HIV/AIDS and Infectious Disease Initiatives. While the December 19th Memorandum authorizes expedited procurement procedures for testing kits, it does not waive source and origin requirements because more research was required on their availability in the United States and the efficacy and cost of offshore testing kits.

Having completed this research, we are seeking your approval of a source and origin waiver from Geographic Code 000 (United States) to Geographic Code 935 for specific testing kits identified in Tab 1. Consistent with the December 19th Memorandum, your approvals below will be in effect through the year 2007 and apply to all sources of funds including prior year funds. Records will be kept on all uses of the waiver authorities. Annual reviews will determine the adequacy of the waiver authorities and their continuing need. The list at Tab 1 will be revised and updated should U.S. manufactured testing kits, or new or improved testing kits from Geographic

Code 935 sources become available that meet USAID program requirements.

Effective counseling and testing for HIV is a critical component of any HIV/AIDS strategy. While testing provides information to individuals regarding their HIV status, it also provides information regarding the extent of the epidemic among target groups and indicates where additional resources may be needed. We anticipate that between one million to three million testing kits will be purchased annually over the seven-year life of the HIV/AIDS initiative. At an estimated average cost of $3 per test, the aggregate procurement value will be approximately 45 to 55 million dollars. However, this amount will be substantially reduced if, as expected, the average cost per testing kit is reduced as new products come on stream.

The applicable statute and regulations covering USAID's "buy America" requirements and pharmaceutical requirements (including testing kits) appear in section 604(a) of the Foreign Assistance Act, ADS section 312.5.3c(2), and in 22 CFR 228. Taken together, these sometimes overlapping regulations provide that pharmaceuticals be purchased outside of the United States only if information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the Food and Drug Administration (FDA) or other U.S. controlling authority. ADS section E312.5.3c(3) adds a further requirement that patent laws be honored. Such items may be purchased in Geographic Code 935 countries if you determine that: 1) the items are not produced or available in the United States, or if available, they cost more than 50 percent of comparable items, or 2) offshore procurement is necessary to promote efficiency in the use of foreign assistance resources and avoid impairment of foreign assistance objectives. While the United States Centers for Disease Control and Prevention (CDC) is not a controlling authority, approval by CDC is good evidence that may be used as a basis for authorizing non-U.S. procurement of products that are not approved by the FDA.

With respect to test kits, the criteria supporting a waiver are met. The most commonly available United States testing kits are based on the Elisa Reader method. The cost per test of these kits is approximately $20. This cost is more than 50 percent higher than the cost of offshore alternatives. Further, these products require high quality lab facilities and highly trained personnel that are not

widely available in target countries. Even where this kind of physical and human infrastructure is available in urban centers, there are insurmountable logistical problems in transporting thousands of blood specimens to and from rural sites to urban laboratories. It takes days or weeks to obtain tests results using the Elisa Reader method. This is too long, given that in some target countries more than 30 percent of clients tested by these systems fail to return for the test results.

Recently, a new "simple-rapid" type of HIV test costing $1-3 per test has become available offshore. These tests are easy to use, no central laboratory is needed, and they deliver test results within a few hours instead of days to weeks. There is currently only one United States-manufactured HIV rapid test that is FDA approved. It costs about $9 and the manufacturer has recently suspended production of this product.

Tab 1 contains a list of testing kits that have been reviewed internally and found to meet all the necessary suitability and price criteria in the applicable waiver regulations cited above. CDC has reviewed and approved the items on the Tab 1 list for safety and efficacy.

RECOMMENDATIONS

A. We recommend that, based on the findings above, you authorize the procurement in Code 935 countries of testing kits identified in Tab 1.

Approve_____

Disapprove_____

Date_____

B. We recommend that you delegate authority to AA/M to amend the Tab 1 approved list from time to time to add new Code 935 testing kits when they meet the same criteria.

Approve_____

Disapprove_____

Date_____

Attachments:

- 4 -

Tab 1 - Approved List of Testing Kit Products and Manufacturers
TAB 2 - December 19, 2000 Action Memo
[Omitted here and reproduced as Annex 7]

- 5 -

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting a source and origin waiver for HIV/AIDS diagnostic testing kits for the HIV/AIDS and Infectious Disease Initiative.

Clearances:

AA/LPA:JCrapa_____Date_____
AA/PPC:TFox_____Date_____
DAA/G:DGillespie_____Date_____
A-AAM:RNygard_____Date_____
GC:SMcAllister_____Date_____
ES:RConroy_____Date_____
M:MWard_____Date_____

Draft:G/PHN:AGetson, RKirkland 12/20/00; Revised GC:RMeighan, MKitay 1/9/01

Tab 1 - Approved List of Testing Kit Products and Manufacturers

Product	Price in Dollars	Source Country	Manufacturer
Bionor	NA	Norway	Bionor A/S
Capillus	$1.50	Ireland	Trinity Biotech*
Determine	$3.80	Japan	Abbott Laboratories*
DoubleCheck	$1.35	Israel	Orgenics
Genie II	NA	France	Sanofi Diagnostics Pasteur
Hema-Strip	$3.00	Singapore	Saliva Diagnostics, Ltd.*
HIV Spot	$1.20	Singapore	Genelabs Diagnostics*
HIVSav	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot	$4.00	France	Sanofi Diagnostics Pasteur*
SeroCard	$1.80	Ireland	Trinity Biotech*
Sero-Strip	$1.50	Israel	Saliva Diagnostic Systems, Ltd.*

* Parent Company is a United States based firm

Annex 7
Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

[Approved by J. Brady Anderson, USAID Administrator, on December 19, 2000, and effective from this date.]

December 19, 2000

ACTION MEMORANDUM

TO: The Administrator

FROM: GC, Singleton B. McAllister
M/OP, Mark Ward

SUBJECT: Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

ISSUE FOR DECISION

Whether to approve the use of other than full and open competitive procurement and exceptions to competition for assistance, as well as other waivers, to facilitate implementation of activities under the HIV/AIDS and Infectious Disease Initiatives.

ESSENTIAL FACTORS

The Global AIDS and Tuberculosis Relief Act of 2000 authorizes funding to combat the worldwide HIV/AIDS epidemic and control the spread of tuberculosis. The FY 2001 Foreign Operations, Export Financing, and Related Programs Appropriations Act, in the Child Survival and Disease Programs Fund account, provides $300,000,000 for HIV/AIDS programs, and $125,000,000 to combat other infectious diseases. Additional funds are appropriated in other accounts.

Congressional findings detailed in the legislation clearly indicate the emergency nature of the situation. HIV/AIDS will soon become the worst epidemic of infectious disease in recorded history. More than 36,100,000 people in the world today are living with HIV/AIDS. 95 percent of the infected population live in the developing world. Of children aged 14 and under, more than 4,300,000 have died

from AIDS and 1,400,000 are living with the disease. In the year 1999 alone 620,000 of those children became infected, 90 percent at birth from mother-to-child transmission (MTCT). Worldwide there have been an estimated 21,800,000 deaths from AIDS, of which more than 80 percent occurred in Sub-Saharan Africa. It is estimated that at the end of 1999, 13,200,000 children had lost at least one parent to AIDS. Some estimates predict that this number of AIDS orphans could increase threefold or more in the next ten years. The U.S. Census Bureau statistics show life expectancy in parts of Sub-Saharan Africa falling to around 30 years of age within a decade, mostly due to HIV/AIDS. In addition, an estimated one-third of the entire world population has been exposed to tuberculosis, which causes about 2 million deaths each year, and new drug-resistant strains are growing rapidly.

USAID's planned response to this crisis in certain defined high and low prevalence countries is outlined in the strategy attached as Tab A ("HIV/AIDS and ID Strategy"), approved by the HIV/AIDS and Infectious Disease Senior Management Team (SMT). Tab A consists of two documents: "USAID's Expanded Response to the Global HIV/AIDS Pandemic, Tuberculosis and Malaria" and "USAID's Expanded Response to the Global HIV/AIDS Pandemic". The HIV/AIDS and ID Strategy, among other things, establishes the following international targets to be accomplished by the year 2007:

1. Reduce HIV prevalence rates among 15-24 year olds by 50 percent in high prevalence countries.

2. Maintain prevalence below 1 percent among 15-49 year olds in low prevalence countries.

3. Provide access to interventions to reduce MTCT to 25 to 50 percent of infected mothers in high prevalence countries.

4. Help local institutions provide care and support to 25 to 50 percent of HIV infected persons in high prevalence countries, and expand access to tuberculosis screening and prevention services as broadly as possible.

These ambitious targets, together with targets related to infectious diseases will require procurement and assistance instruments to be in place in the shortest possible time. Though full and open competition works well to maximize participation by the private sector community, we will need expedited action to meet the targets. This concept is echoed in the Conference Report accompanying the FY 2001 Appropriations Act that states:

3

> "The managers are aware that the HIV/AIDS and tuberculosis crises require extraordinary efforts on the part of the United States Government. USAID is encouraged to use, as appropriate, its existing waiver authorities regarding financing and procurement of goods and services, and grant making, in order to expedite the provision of HIV/AIDS and tuberculosis assistance and enhance the efficiency of that assistance."

As directed by the SMT in its meeting on November 9, 2000, certain actions needed to expedite the USAID response will be pursued by GC and OP for approval at lower levels. Those actions include:

1. Increasing the numbers of experienced contracting officers (COs) in Washington and the field dedicated to the Initiatives by rehiring former USAID and other federal agency COs under personal service contracts (PSCs) or on expert/consultant status, and delegating to them authority to sign contracts, grants and cooperative agreements. Although such individuals are not normally given authority to sign A&A instruments, exceptions to this restriction may be approved by AA/M. Consideration will also be given to obtaining the services of experienced contracting officers through a Cooperating Agency Service Unit or Franchise Business Activity (CASU/FBA).

2. Authorizing the use of other than full and open competition to hire PSCs for HIV/AIDS and infectious disease work overseas. This would represent a return to USAID's pre-1997 policy for PSC hiring. It would enable USAID missions to obtain required technical help in the shortest possible timeframe.

3. Ensuring the maximum use of existing authority in ADS 321 to award grants to Minority Serving Institutions using less than fully competitive procedures.

4. Ensuring maximum use of existing authorities to award contracts to 8(a) firms, small businesses, and small and disadvantaged businesses using less than fully competitive procedures.

5. Increasing the grant making authority of USAID mission directors to $2,000,000 for use in circumstances when services of an Agreement Officer are not readily available, subject to legal and procurement office local staff review. (If necessary, ad hoc delegations can be requested in a greater amount).

6. Making maximum use of "wholesale" instruments such as grants-under-contracts (with the authorized dollar amount of grants increased to an appropriate amount), umbrella grants, leadership/associate assistance instruments, indefinite quantity contracts, and other arrangements designed to provide fast track assistance and contracting.

7. Reviewing the technical feasibility of some procurement of pharmaceuticals, testing kits, and condoms from non-U.S. sources, if required for timely program implementation. Waiver documentation will be developed as soon as possible based on the results of this review.

In addition we recommend that you approve the following blanket waivers which will both expedite specific activities and signal the sense of special urgency felt at the highest level. The waivers would be effective immediately and would remain in force throughout the life of the HIV/AIDS and ID Strategy, estimated to be through the year 2007. The waivers would cover activities funded from all sources of funding (e.g., SEED or ESF funding) and U.S.-owned local currency accounts. The waivers would apply to prior year funding still in the pipeline as well as future fiscal year appropriations. Specific guidance to be developed by GC and OP and approved by the SMT will specify when the use of the waiver authorities is most appropriate. Records will be kept on all uses of the waiver authorities. The situation will be reviewed on an annual basis to determine the adequacy of the waiver authorities or their continuing need.

Normal USAID waiver authorities will, of course, also remain available for use in situations where they are needed to meet program objectives, e.g., the authority recommended in Section B(1) below authorizing an extension of grants and cooperative agreements for up to a two-year period, would not preclude a waiver for a longer period authorized pursuant to ADS 303.5.5(d)(1).

RECOMMENDATIONS

A. Approval of Obligations Not Covered by Existing Strategic Objectives (SOs). Existing approved Strategic or Special Objectives may not cover some activities contemplated by the HIV/AIDS and ID Strategy. ADS 201.3.3.5 provides that in special foreign policy situations where it is necessary to initiate activities prior to completion and approval of a strategic plan, a temporary one-year exemption may be issued. We recommend that you approve such a one-year exemption for all HIV/AIDS and Infectious Disease

5

Initiative activities contemplated by the HIV/AIDS Strategy.

Approve:_____

Disapprove:_____

Date:_____

B. Grants and Cooperative Agreements. Authorization For Other Than Fully Competitive Procedures. In order to meet the HIV/AIDS and ID Strategy targets, USAID must select its grant-financed partners and get them operational in the shortest possible time frame. For this purpose we recommend:

1. Authorizing non-competitive amendments to existing grants and cooperative agreements for additional work similar to that performed under the original agreement. These extensions would be limited to a two-year period, in order to provide the time to obtain subsequent support on a more competitive basis.

2. Authorizing awards of new grants and cooperative agreements using less than fully competitive procedures. This authority would extend to all types of grants and cooperative agreements, including Leader/Associate awards for Leader/Associate Assistance instruments provided they include pre-award established ceilings. While formal advertising would not be required, applications would be solicited from as many sources as practicable under the circumstances.

Pursuant to ADS 303.5.5(d)(5) competition is not required for assistance awards when justified by circumstances which are determined to be critical to the objectives of the foreign assistance program. Based upon the global life-threatening nature of the HIV/AIDS and infectious disease epidemics we recommend that you make this critical objectives finding and authorize the use of other than fully competitive procedures in making awards under the above described assistance instruments.

Approve:_____

Disapprove:_____

Date:_____

C. Procurement of Goods and Services. Authorization For Other Than Full and Open Competition. We recommend that flexible and expedited procurement procedures be approved for USAID direct contracting for the delivery of goods and services. Specifically, we recommend that such procurement be undertaken through limited competitive procedures that are quicker as well as less labor intensive than the FAR full and open competitive procedures. As in (B) above, this would apply to follow-on extensions of existing contractual efforts, as well as to new procurements.

Under the USAID Acquisition Regulations (AIDAR) the Administrator of USAID may determine in writing, with supporting findings, that compliance with full and open competitive procedures would impair foreign assistance objectives and would be inconsistent with the fulfillment of the foreign assistance program. AIDAR 706.302-70(b)(3)(ii). As USAID Administrator, you have the authority to make such a determination with respect to entire programs, such as the HIV/AIDS and Infectious Disease Initiatives. The expedited procedures would be utilized for quick reaction activities where the impact of U.S. assistance will need to be evident in a very short time frame. Your approval below will also serve as approval of the formal written determination with supporting findings at Tab B. The Agency Competition Advocate has reviewed the determination. While formal advertising would not be necessary, solicitation would be made from as many sources as practicable under the circumstances. However, in the case of follow-on extensions, it is understood that the existing contractor is the only practicable source.

Approve:
Disapprove:
Date:

D. Use of Small Businesses, Small Disadvantaged Businesses, and Minority Serving Institutions. We think that it is important at the outset of the program to have a formal statement issued by top Agency management on the [U1] importance of including Small Businesses, Small Disadvantaged Businesses, and Minority Serving Institutions (MSIs) in the implementation of these initiatives. In that statement, Agency staff would be reminded that legal mechanisms now exist to make awards to these firms and

institutions using other than full and open competition — namely, by using: 1) set-aside authority under the Small Business Act to make awards to Small Businesses and to 8(a) Small Disadvantaged Businesses, and 2) the authority contained in USAID's Automated Directives System (ADS) Section 321 to award grants and cooperative agreements to MSIs via limited competition among these institutions. The inclusion of such information in the statement would help offset any downward trend in USAID in contracting with Small and Small Disadvantaged Businesses, similar to the trend verified government-wide in a study commissioned by the SBA and by recent USAID reports on MSIs submitted to the White House and OMB. The decline government-wide has been attributed to the agencies' use of IQC's and of bundling of government contracts. We recommend that as soon as decisions contained in this memorandum are made, we prepare such a statement for your signature for distribution to USAID staff.

Approve:
Disapprove:
Date:

E. Source and Origin Waiver. Under the Development Fund for Africa legislation, Development Assistance (DA) and Child Survival and Disease (CSD) funding utilized for activities in Africa enjoy a liberalized source and origin requirement. Normal USAID source/origin/nationality requirements do not apply to procurements made with that funding. As a matter of policy, procurement from the United States is maximized whenever practicable, consistent with program objectives. We recommend that Geographic Code 935 (which includes all countries, excluding only the foreign policy restricted countries) be established as a pre-authorized source/origin/nationality code for any goods and services procured under the HIV/AIDS and ID Strategy, in accordance with an order of preference requiring U.S. procurement to the extent practicable.

As is the present case in Africa, motor vehicles would be included in the waiver, and your approval below constitutes the "special circumstance" finding required by FAA 636(i), for vehicles procured for the HIV/AIDS and Infectious Disease Initiatives. However, procurement of motor vehicles from non-U.S. sources will be held to an absolute minimum, and done only when necessitated by required specifications, spare parts, and maintenance

capabilities. As is the present case in the Africa Bureau, pharmaceuticals are not covered under the waiver. However, as indicated above, OP, GC and others will be reviewing the technical feasibility of, and preparing separate waiver documentation for, some procurement of pharmaceuticals, testing kits, and condoms from non-U.S. sources, if required for timely program implementation.

22 CFR 228.51(a)(3) and 22 CFR 228.53(c) provide that a source and origin waiver for goods or services may be authorized when it is found necessary to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives. The regulation, as well as the underlying statute (FAA 636i), provides that such waivers must be made on a "case-by-case" basis, and GC confirms that this waiver limited to the HIV/AIDS and ID Strategy meets that standard.

We recommend that you make the above finding and authorize the waiver of source and origin requirement for goods and services purchased for the HIV/AIDS and Infectious Disease Initiatives to be made from Geographic Code 935, as discussed above.

Approve:
Disapprove:
Date:

[Tab A, USAID's Expanded Response to the Global HIV/AIDS Pandemic, Tuberculosis and Malaria, is available at http://www.usaid.gov/pubs/ads/300/updates/iu3-0101.doc.]

Tab B

DETERMINATION AND FINDING:

USAID Administrator's Determination Regarding Procurement Procedures for Activities for the HIV/AIDS and Infectious Disease Initiatives

Pursuant to the authority set forth in the USAID Acquisition Regulations, Section 706.302-70 (b) (3) (ii), I have determined that it is necessary to use other than full and open competitive procedures for the activities which USAID finances for the HIV/AIDS and Infections Disease Initiatives in order to avoid impairment of foreign assistance and U.S. foreign policy objectives. This determination is made in consideration of the supporting findings set forth below and will be effective from the date of signature, and subject to annual review will remain in force for the period of the Initiatives, estimated to be through the year 2007. Notwithstanding this determination, USAID will seek offers in particular procurements, from as many potential offerors as is practicable under the circumstances.

Supporting Findings:

Congress recently passed the Global AIDS and Tuberculosis Relief Act of 2000, which in conjunction with the FY 2001 Appropriations Act, provides USAID with resources to combat the HIV/AIDS and Infectious Disease epidemics now raging in the developing world.

The conference report accompanying the FY 2001 Appropriations Act emphasizes the emergency nature of the crises, and urges USAID to use existing waiver authorities regarding financing and procurement of goods and services in order to expedite assistance and enhance the efficiency of the program.

The current HIV/AIDS epidemic is the largest infectious disease epidemic ever known in recorded history, by far more devastating than the bubonic plague of the 1300s, and even greater than the worldwide influenza epidemic of 1918-1919.

In Africa alone over 5,000 persons die every single day from AIDS or AIDS related illnesses, and each year 600,000 children worldwide are infected with the disease, almost all of them through mother to child transmission.

As much as one-third of the entire world population has been exposed to Tuberculosis, and new strains are increasingly being

discovered with substantial drug resistant characteristics to medicines currently in use. Nearly 2 million people die each year from TB, and the spread of the TB epidemic is being fueled by the HIV/AIDS pandemic; persons with HIV/AIDS are 30 times more likely to develop TB.

The administrative and time consuming burdens of using fully competitive procedures will not allow USAID to respond to the crises in an effective and efficient fashion.

USAID can achieve an important measure of competition informally by seeking offers from as many sources as practicable under the circumstances.

Prior to using informal competitive procedures for a particular procurement, as authorized by this determination, requesting offices will consider the feasibility of using FAR full and open competitive procedures, as well as small business Section 8(a) procurement authorities and minority serving institutions.

All uses of this authority will be documented, and the situation will be reviewed on an annual basis to determine the adequacy of the authorities, their continued necessity, or any need for their modification.

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting decision on Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

Clearances:

AA/LPA:JCrapa Draft date 12/14/00
AA/PPC:TFox Draft date 12/15/00
A-AA/G:BTurner Draft date 12/15/00
AA/AFR:VLowery-Derryck Draft date 12/15/00
AA/E&E:Dpressley Draft date 12/15/00
AA/ANE:RRandolph Draft date 12/14/00
A-AA/LAC:CLeonard Draft date 12/15/00
AA/BHR:HParmer Draft date 12/14/00
A-AA/M:RNygard Draft date 12/15/00
GC:Pramsey _____ date _____
ES:RConroy _____ date _____

GC:RMeighan:LGray:12/04/00:25874:HIV2; revised GC:MKitay;12/19/00

Annex 8
Sample Request for Approval for Non–U.S. Source/Origin HIV Test Kit

FAMILY HEALTH INTERNATIONAL

November 13, 2000

Mr. Robert Samuel Taylor
Administrative Agreement Officer
M/OP/A/HRN
Office of Procurement
U.S. Agency for International Development
Washington, D.C. 20523 1427

Subject: Cooperative Agreement **HRNA00970001700 (IMPACT):** Request for Approval to Purchase Rapid HIV/AIDS Test Kits and COMS approval for Geographic Code 935 for the HIV Voluntary Counseling and Testing (VCT) program in Rwanda

Dear Mr. Taylor:

Under the approved USAID/Kigali IMPACT scope of work (SOW), the VCT program is required to provide rapid HIV/AIDS diagnostic tests for clients in both rural and urban clinics. To fulfill this requirement, FHI has previously sought and obtained approval for the locally financed procurement of Determine, Genie II and Bionor HIV 1 / 2 test kits. Subsequently, USAID/Rwanda has requested that the VCT sites be expanded from the current four to ten by the end of FY 2001. The additional logistical considerations of providing this expanded service require us to request the Office of Procurement, COMS division to review the following information and to approve the purchase of *HIV Spot* HIV/AIDS test kits from Genelabs Diagnostics.

Discussion: The only available US manufactured, FDA approved HIV/AIDS test methodologies available for use in Rwanda are based on the ELISA Reader technique, which is not a rapid test. This technique requires batching, a sophisticated laboratory and equipment, and cannot be done during the patient's visit. It has been noted that in Rwanda, from 3038% of clients tested by the ELISA technique fail to return for the test results. Also, the logistical problem created by the need to transport blood from rural sites to urban laboratories and then to deliver the test results back again, is not an economical use of USAID funds. As has been previously demonstrated and agreed to by USAID, for the Rwanda HIV VCT Program to be successful, rapid HIV testing is required. Of the rapid tests that are currently employed in the VCT program, all require refrigeration. This is the logistical problem to which I referred earlier.

Field testing of rapid HIV tests by the Rwanda National Reference Laboratory was completed in early 2000. Their recommended testing algorithm requires an initial test to be performed with the *Determine* (Abbott Laboratories) rapid test. Initial positive samples are followed by a second test. Rwanda currently recommends the use of Genie II (Sanofi Diagnostics), HIV Spot, Bionor HIV1/2 (Bionor) or Hexagon HIV (Human). HIV Spot is the only one of these four tests that does not require refrigeration. Storage is an important concern for the Rwanda VCT program. There is limited refrigerator space available at the National Lab, and many of the VCT sites, planned under the expanded program, do not have a reliable electrical supply.

Headquarters:
P.O. Box 13950, Research Triangle Park, NC 27709 USA
2224 E. NC Highway 54
Durham, NC 27713 USA
Telephone: 9195447040 Fax: 919-544-7261

Washington Office:
HIV/AIDS Prevention and Care Department
2101 Wilson Boulevard, Suite 700
Arlington, VA 22201 USA
Telephone: 703-516-9779 Fax: 703-516-9781

URL: http://www.fhi.org

Authority: Pursuant to Standard Provision 3.11, *USAID Eligibility Rules for Goods and Services (MAR 1977),* subsection (a)(3)(iii), the prior budget approval of the Agreement Officer is required before FHI may purchase pharmaceuticals. Subsection (a) refers to ADS Chapter 312 as the source of USAID's policies on restricted commodities such as pharmaceuticals.
ADS 312.5.3c states that, to be eligible for USAID financing, pharmaceuticals must comply with regulations issued by the FDA or other controlling US authority governing interstate shipment of such products, unless M/OP/COM approves the procurement prior to financing. Proposed pharmaceutical procurements for M/OP/COM approval must include the generic name, dosage form, strength or concentration, unit package size, the intended therapeutic use, name of the manufacturer, and any other relevant factors bearing upon a specific application.

Pharmaceuticals must also normally be of US source and origin. USAID has already authorized the 935 Geographic Code for commodities not produced or otherwise available in the United States (May 4, 1998 letter from Mr. Emmanuel E. Atsalinos, attached). However, the Office of Procurement, COMS division must review and approve each 935 procurement according to the criteria listed below.

935 Pharmaceutical Procurement Criteria:

The pharmaceutical is essential for the activity
Justification: The Rwanda VCT program requires a rapid testing technique for HIV/AIDS detection that does not require refrigeration and therefore HIV Spot is essential to the activity as described above.

The product, in the same or substantially equivalent form, is not available from the US, or the delivered price would be at least 50% more than from another source
Justification: As noted above, currently there are no US manufacturers producing FDA approved rapid diagnostic test kits for HIV/AIDS detection.

Information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the US FDA or other controlling US authority
Justification: HIV Spot has been evaluated by WHO and has been reported on in numerous peerreviewed journals. These evaluations have shown the test to meet with stringent criteria and demonstrate that it is comparable to the standard ELISA and Western Blot in terms of sensitivity and specificity. Conclusions of these analyses have been included for review.

Any nonUS pharmaceutical product procured may not violate US patent laws
Justification: There are no US manufacturers making FDA approved rapid test kits in the U.S.A. As an additional safeguard, FHI will require the manufacturers to certify on their invoices that the items supplied will not infringe any US patents.

Information related to USFDA standards comparisons:

A World Health Organization assessment of the operational characteristics of commercially available HIV rapid test kits found *HIV Spot* to have a sensitivity of 99.3% (95% confidence interval 97.4 – 99.9) and a specificity of 100% (95% confidence interval 98.5 – 100)[5]. It was rated easy to use and very suitable for use by small laboratories. Only 1% of the samples tested with *HIV Spot* had indeterminate results.
Studies in Burkina Faso and Ethiopia showed similarly high sensitivities and specificities for *HIV Spot*, and recommended use of the test in settings where western blot and enzymelinked immunoabsorbant assays (ELISAs) are not available[1,4]. Two studies comparing HIV test kits using seroconversion panels found *HIV Spot* to have a specificity approaching 100%[2,3].

Two year cost for this test is estimated at $122,512. and is based upon a unit cost of $1.90 per test. Estimates are based upon projected numbers of clients per day at ten clinic sites with projections of HIV rate for estimating the numbers of confirmatory tests.

Your approval is requested with the understanding that sufficient funds exist under the referenced contract for the proposed purchase; this request is within the terms of the contract; and that your approval will not increase the overall cost of the contract nor change or modify its terms. Please contact Dr. Gina Dallabetta, Director of Technical Support (703) 5169779 or me at (919) 4051455 if you require any additional information.

Thank you for your consideration.

Sincerely,
Bob Mohar
Manager of Purchasing
and Administrative Services

cc: Mr. Alan Getson, COTR/USAID
Mr. Paul DeLay, G/PHN/HN/HIVAIDS
Larry Origlio, Deputy Director of Finance
Gina Dallabetta, Director, Technical Support/Prevention
Maggie Diebel, Associate Director, Field Programs
Deborah Murray, Resident Advisor, FHI/Rwanda
Sujata Rana, Senior Program Officer
Ofelia GuerreroKirlin, Contracts Officer

U.S. Agency for International Development, Washington, DC 205231427

RECEIVED
MAY 06 1998
FINANCE & ADMINISTRATION

May 4, 1998

Family Health International
Attn: Mr. Max Gonson, Senior Contracts Manager
2101 Wilson Boulevard, Suite 700
Arlington, VA 22201

Subject: Cooperative Agreement HRNA00970001700
Waiver to Purchase US FDA Approved, US Source and Origin Pharmaceuticals

Dear Mr. Gonson:

Thank you for your letter of February 27, 1998, requesting blanket approval to purchase, when needed, US Food and Drug Administration approved pharmaceuticals under the subject Cooperative Agreement.

The language as stated in ADS 312.5.3c(1) indicates that "To be eligible for USAID financing, all pharmaceutical and biological products, including oral rehydration salts, must comply with the U.S. Food and Drug Administration (or other controlling U.S. authority) regulations governing United States interstate shipment of such products....". In addition, ADS 312.5.3c(2) states that (T)he source and origin of USAID financed pharmaceuticals is limited to the United States."

Thus, the ADS allows for the purchase of US FDA approved, US source and origin pharmaceuticals, although the Cooperative Agreement, in section 3.13 indicates that prior written authorization is necessary from the Grant Officer, when purchasing restricted goods, in this case, pharmaceuticals.

The Administrative Agreement Officer hereby provides prior written authorization for all US FDA approved, US source and origin pharmaceuticals, as long as the pharmaceutical purchase is reviewed and approved technically by the USÀID Office of Health and Nutrition, Division of HIVAIDS, as part of the annual work plan or as part of the monitoring process done with USAID Missions before funds are added into the Cooperative Agreement.

Notwithstanding the above, a Source/Origin waiver for selected pharmaceuticals for sexually transmitted diseases (STD) and opportunistic infections (OI), signed December 15, 1997, approved geographic code 935 to allow the procurement of selected STD pharmaceuticals for the treatment of STDs and OIs. This shift from geographic code 000 to geographic code 935 allows 935 countries as authorized source/origin for pharmaceuticals for the HIV/AIDS SO 4 Results Package.

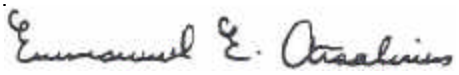
The 935 geographic code is authorized when the commodity is not produced or available in the US; it is necessary to permit procurement in a country not otherwise eligible due to some unforeseen or emergency circumstance; or the

procurement is necessary to promote efficiency in the use of US foreign assistance resources. In addition, the Office of Procurement, COMS division must review and approve each 935 pharmaceutical procurement for the following criteria: (1) the pharmaceutical is essential to the activity; (2) the product, in the same or substantially equivalent form, is not available from the US, or the delivered price would be at least 50% more than from another source; (3) information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the US FDA or other controlling US authority; and (4) any nonUS pharmaceutical product procured may not violate US Patent laws.

Requests for approval for 935 geographic code pharmaceuticals should be addressed to the Agreement Officer, with a courtesy copy to the USAID Office of Health and Nutrition, Division of HIVAIDS.

If there are any questions regarding this letter, please contact me on (202) 712 1039 or by email at "matsalinos@usaid.gov".

Sincerely,



Emmanuel E. Atsalinos
Admin. Agreement Officer
M/OP/A/HRN
Office of Procurement

cc: P. DeLay, G/PHN/HN/HIVAIDS

doc: a7017pha.rma

Published Literature on the HIV Spot Rapid HIV Test

Study Author	Site	Other rapid/simple tests compared by study	Sera used	Sensitivity of HIV Spot	Specificity of HIV Spot	Conclusion
Meda N et al.[1]	Burkina Faso	CombAIDS-RS (Span Diagnostics Ltd) Multispot HIV-l/HIV-2 (Sanofi Diagnostics Pasteur)	768 serum samples from blood donors, patients with AIDS, and pregnant women	98.2% (98.2-99.3)	100% (99-100)	Of the 3 rapid tests evaluated, HIV Spot had the lowest sensitivity and highest specificity. WHO minimal norms for HIV commercial tests used in diagnosis strategies are a sensitivity of 99%. HIV Spot was therefore not recommended.
Constantine et al.[2]	ITM in Antwerp, Belgium	Immunocomb Bispot (PBS) Orgenics) Serodia HIV- 1 (Fujirebio)	Total of 11 sero-conversion panels obtained from 2 commercial US-based sources	99.3% (97.4-99.9)	Not calculated	All 8 tests showed differences in sensitivity when evaluated in a highly controlled setting, but the differences are smaller than those observed in field settings. All tests evaluated are appropriate for use as screening tests.
Constantine et al.[3]		HIVCHEK System 3 (Ortho Diagnostics) A/Q Rapid HIV (Bionike Labs.) Genie II HIV-1/HIV-2 (Sanofi Diagnostics) Quix HIV-1-2-O Rapid Blood Test (Universal HealthWatch) Immunocomb II HIV 1&2 BiSpot (Orgenics) Serodia HIV-1/2 (Fujirebio)	68 HIV-1 and HIV-2 samples from several countries in Africa and the Far East (multiple clades)	HIV-1 group M: 100% HIV-1 group O: 100% HIV-1/2: 100% HIV-2: 83.3%	Not calculated	Most of the 7 tests evaluated produced excellent results. Recommends studies incorporating a larger number of samples representative of HIV variants.
Tegbaru et al.[4]	Ethiopia	None – all other tests were ELISAs	265 sera from hospital patients, commercial sex workers, blood donors and scholarship winners	98.7% (95.4-99.8)	98.2% (93.5-99.8)	All tests evaluated had good sensitivity, specificity, positive predictive value and test efficiency. Ease of performance and suitability for use in small blood bank collection centers was higher for HIV Spot than for the ELISAs.
WHO[5]		30 other tests since 1989	Seroconversion panels with serum samples from all parts of the world	99.3% (97.4-99.9)	100% (98.5-100)	HIV Spot is easy to perform and very suitable for use in small laboratories.

1. N. Meda, L. GautierCharpentier, R.B. Soudré, H. Dahourou, R. Ouedraogo-Traoré, A. Ouangré, A. Bambara, A. Kpozehouen, H. Sanou, D. Valéa, F. Ky, M. Cartoux, F. Barin, & P. Van de Perre. **Serological diagnosis of human immunodeficiency virus in Burkina Faso: reliable, practical strategies using less expensive commercial test kits.** *Bulletin of the World Health Organization* 1999. 77: 731-739.

2. Constantine NT. Van der Groen G. Belsey EM. Tamashiro H. **Sensitivity of HIVantibody assays determined by seroconversion panels.** *AIDS* 1994, 8:17151720.

3. Constantine NT. Zekeng L. Sangare AK. Gurtler L. Saville R. Anhary H. Wild C. **Diagnostic Challenges for Rapid Human Immunodeficiency Virus Assays:** ***Performance Using HIV-1 Group O, HIV1 Group M, and HIV2 Samples.*** *Journal of Human Virology* 1997, 1:4652.

4. Tegbaru B. Meles H. Fisseha B. Mekonnen Y. Haile H. **Evaluation of five commercial assays for detecting HIV1 and 2 antibodies, Addis Ababa.** *Ethiopia Journal of Health and Development*; 1999. (13) 175180.

5. WHO/UNAIDS. **Operational characteristics of commercially available assays to determine antibodies to HIV1 and/or HIV2 in human sera, report 11.** 1999. Geneva, Switzerland.

Annex 9
Sample Request for Approval for Non–U.S. Source/Origin Drug

ACTION MEMORANDUM

TO: DAA/G/PHN, Duff Gillespie

FROM: G/PHN/HN, Joy Riggs-Perla

SUBJECT: Source/Origin/Nationality Waiver for the Procurement of Vaccine through the Ani & Narod Memorial Fund (ANMF) Endowment

Issue: Your approval is required for a source/origin/nationality waiver from Geographic Code 000 to Geographic Code 935 to permit the procurement of vaccines and syringes from nonU.S. manufacturers with Agency funds obligated to the ANMF Endowment. The endowment would procure vaccines and syringes through UNICEF for the Ministry of Health (MOH) in Armenia.

Background: In 1999, G/PHN/HN was approached by the Ani & Narod Memorial Foundation (ANMF), a U.S. based NGO with the mission of "Assisting Armenian women and children to live fuller, happier and healthier lives". ANMF proposed to develop a longterm endowment that would fund childhood vaccines and syringes for the Armenian MOH. Once established, interest from the endowment would purchase the vaccines indefinitely. Funding for the endowment corpus ($1.4 million) would come from a combination of USAID, the Armenian Diaspora and other donors. G/PHN/HN and USAID/Yerevan are preparing to obligate a total of $400,000 to the endowment as it would create a sustainable supply of vaccine and provide the opportunity to support and influence a new approach to creating sustainable vaccine supplies.

ANMF has the organizational capacity to create and manage the endowment, but lacks the inhouse capacity to forecast, procure, distribute or ensure the quality of procured vaccine. Procuring vaccines and syringes through UNICEF is the safest and most reasonably priced approach for ANMF. ANMF is not familiar with the complex vaccine procurement process, whereas UNICEF routinely serves as the procurement agent for countries around the world. Working through UNICEF would ensure the procurement of vaccines of known quality along with providing a delivery system that would maintain this quality during transport. Lastly the UNICEF price structure makes the endowment economically feasible, whereas the prices of U.S. manufacturers render the endowment impossible for ANMF (See attachments: vaccine price list).

Along with UNICEF, ANMF is a member of the National Immunization Coordinating Committee (NICC) in Armenia, which provides the forum for determining the projected annual vaccine needs in accordance with the National Immunization Plan. Therefore, a source/origin/ nationality waiver is requested from Geographic

Code 000 to Geographic Code 935, which would allow USAID investments in the ANMF endowment to provide vaccine and syringes to Armenia that have been procured using the process established by UNICEF.

Justification

The approved Geographic Code for Source, Origin and Nationality for endowments is "000" (U.S.A. only). However, according to ADS 310.5.5, USAID may expand the authorized Geographic Code, or otherwise agree to finance procurements, which do not meet the requirements of 22 CFR 228, by processing a waiver.

ADS E312.5.3(c)(2)(a), states that a waiver of U.S. source policy, for assistance other than Commodity Import Programs (CIPs), will be considered if "1) the pharmaceutical product is essential to the activity; 2) the product, in the same or substantially equivalent form, is not available from the United States, or the delivered price from the United States would be at least 50 percent more than from another source; and 3) information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority."

1) In response to ADS E312.5.3(c)(2)(a)(1): vaccine is essential to the activity, as the sole purpose of the endowment is to address the vaccine shortage in the country through the funding and procurement of vaccine. Additionally, autodisable syringes are required in order to ensure that the supplied vaccine can be administered safely.

2) In response to ADS E312.5.3(c)(2)(a)(2): as stated above the procurement of vaccines from U.S. manufacturers would increase the price from six to 22 fold and, as a result, ANMF would not be able to establish an endowment as the core funding would become astronomical. (See attachment: vaccine price list)

3) In response to ADS E312.5.3(c)(2)(a)(3) UNICEF is recognized globally for providing vaccine of "known good quality". All manufacturers that desire to respond to UNICEF solicitations must be preapproved by the World Health Organization (WHO) and annually demonstrate that they comply with the standards set by the WHO. The Vaccine Supply and Quality (VSQ) section of the Global Programme for Vaccines and Immunization (GPV) at WHO Geneva Headquarters acts as an adviser to UNICEF on matters related to the quality of vaccines and has formulated criteria for evaluating the acceptability of vaccines for purchase by UN agencies (See attachment: Procedure for

assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies). All quality assurance functions are provided to UNICEF by WHO. These include random lot testing, inspection of the supplier's facility and the National Control Authority Laboratory by qualified experts, periodic reinspection and followup investigation of adverse events reported.

Governments that lack a functioning National Regulatory Authorities (NRA) to ensure vaccine quality are encouraged by WHO to procure through UNICEF in order to ensure the provision of vaccine of known quality. The Government of Armenia lacks a NRA capable of ensuring the procurement and receipt of quality vaccine. ANMF, as an institution, lacks the technical capacity to implement the complex vaccine procurement process or address the issue of quality. Procuring through UNICEF is the most effective means to ensure that vaccine of known quality is procured. Procuring syringes through UNICEF would also ensure a supply of autodisable syringes and safety boxes for their disposal. The U.S. syringe manufacturers, UNIVEC and Becton Dickson, are the primary suppliers for UNICEF. Therefore, procuring syringes through UNICEF supports the procurement of U.S. manufactured syringes.

Authority

Pursuant to ADS 103.3.16.2, G/DAAs have been delegated the authority to waive source, origin and nationality requirement for the procurement of goods and services in accordance with ADS 103.3.8.(a).

RECOMMENDATION

For the reasons outlined above, it is recommended that you sign below, thereby approving a waiver of source, origin and nationality from Geographic Code 000 to Geographic Code 935 to permit Agency funds obligated to the ANMF endowment to procure vaccine and autodisable syringes through UNICEF.

Approve

Disapprove

Date

Attachments:

1 - Vaccine Price list

2 - Procedure for assessing the acceptability, in principle

vaccines for purchase by United Nations agencies

ATTACHMENT 1

VACCINE PRICE LIST

UNICEF VS U.S. MANUFACTURES
Price Per Dose in U.S. Dollars

Vaccine	UNICEF	U.S. Manufacture
Diphtheria, pertussis, tetanus (DPT)	0.075	1.71
Tuberculosis (BCG)	0.095	N/A
Measles, mumps, rubella (MMR)	0.489	2.80
Oral polio	0.082	1.52

Prices obtained from the UNICEF Supply Division in Copenhagen and the U.S. Centers for Disease Control and Prevention, National Immunization Program.

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting decision on Source/Origin/Nationality Waiver for Vaccine Purchased under the ANMF Endowment

Clearances:

G/PHN/HN/CS;RGreene_____ Date
G/PHN/HN;LHollis_____ Date
G/PHN/HN;PEhmer_____ Date
G/PHN/OFPS;LThompson_____ Date
AAA/G/PHN;RKirkland_____ Date
M/OP/TC/COM;BGreen_____ Date

G/PHN/HN:EWainwright:EW:7124569:11/07/00:
[935 waiver.doc]
G/PHN/HN:MTrostle:7121276
G/PHN/HN:Megan Fotheringham:6610366

Annex 10
List of International Suppliers/Agencies

List of International Suppliers/Agencies

This annex is not intended to be a comprehensive list of all international suppliers/agencies and inclusion in this list does not imply that the supplier/agency is endorsed by USAID or RPM Plus or preferred over any other international supplier/agency.

ACTION MEDEOR
Deutsches Medikamenten-Hilfswerk
St. Töniser Strasse 21
D-47918 Tönisvorst
GERMANY
Phone: (49-2156)-97-88-0
Fax: (49-2156)-80632
Telex: 853 1064 AMED
E-mail: **info@medeor.org**
URL: **http://www.medeor.org/**

ECHO - (ECHO International Health Services Limited)
Ullswater Crescent
Coulsdon Surrey CR5 2HR
UNITED KINGDOM
Phone: 44-181-660-2220
Fax: 44-181-668-0751
E-mail: **cs@echohealth.org.uk**
Other: ECHO serves nonprofit humanitarian projects only.

IDA - (International Dispensary Association)
P.O. Box 37098
1030 AB Amsterdam
THE NETHERLANDS
Phone: 31-20-403-3051
Fax: 31-20-403-1854
E-mail: **ida_sale@euronet.nl**
URL: **http://www.euronet.nl/users/ida_tran**
Other: IDA only serves nonprofit organizations and governments.

Missionpharma A/S
Vassingeroedvej 9
DK-3540 Lynge
DENMARK
Phone: 45-48-16-32-00
Fax: 45-48-16-32-48
Telex: 40654 relief dk
E-mail: **info@missionpharma.com**
URL: **http://www.missionpharma.com**

ORBI-PHARMA
Molenberglei 18
B- 2627 Schelle
BELGIUM
Phone: 32-3-880-63-60
Fax: 32-3-888-74-81
E-mail: **orbi@glo.be**

Tri-Med
7 Hanson Street
London W1P 7LJ
UNITED KINGDOM
Phone: 44-20-7637-1601
Fax: 44-20-7255-1000
E-mail: **London@tri-med.com**
URL: **http://www.trimed.com**

UNICEF - (United Nations Children's Fund)
UNICEF Plads - Freeport
DK-2100 Copenhagen 0
DENMARK
Phone: (35)-273527
Fax: (35)-269421
Telex: 19813
E-mail: **supply@unicef.dk**
URL: **http://www.unicef.org**
Other: HIV/AIDS-related pharmaceutical products: information on suppliers or products is available from Hanne Bak Pedersen, UNICEF, Supply Division
E-mail: **hpedersen@unicef.dk**
Fax: (35)-27308

UNICEF procures supplies in support of UNICEF program goals, either for UNICEF country officials or for authorized procurement services customers. The latter are generally development banks, aid agencies, or NGOs and UNICEF provides prices and terms directly to them. The requests are processed through UNICEF field offices to ensure that the project is in direct support of the UNICEF goals in a given country. There are minimum order specifications and handling fees and cooperating agencies may be required to pay for orders in advance. Organizations interested in procurement services may contact the Supply Division directly.

Annex 11
List of Manufacturers of Selected HIV Test Kits

List of Manufacturers of Selected HIV Test Kits

This annex is not intended to be a comprehensive list of manufacturers of all HIV test kits and inclusion in this list does not imply that the manufacturer and/or the HIV test kit is endorsed by USAID or RPM Plus or preferred over any other manufacturer and/or HIV test.

BIONOR™ HIV 1&2

Bionor A/S
P.O. Box 1868
Gulset,
N-3703 Skien
NORWAY
Contact: Mr. Birger Sørenson
Phone: +47-3550-5750
Fax: +47-3550-5701
E-mail: **birger.sorenson@bionor.no** or
bionor@bionor.com
URL: **http://www.bionor.no**

Capillus™ HIV

Trinity Biotech Plc
IDA Business Park
Bray, Co Wicklow
IRELAND
Contact: Marie McCarthy, Group Product Manager
Phone: +353-1-276-9828
Fax: +353-1-276-9881
E-mail: **mmcarthy@trinitybiotech.ie** or
info@trinitybiotech.ie
URL: **http://trinitybiotech.com**

Determine™ HIV-1/2

Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064
USA
Contact: Friedah Nehmadi
Phone: +1-847-935-8771
Fax: +1-847-937-0912
E-mail: **friedah.nehmadi@abbott.com**
URL: **http://www.abbottdiagnostics.com**

DoubleCheck™ HIV 1&2
Orgenics Ltd
P.O. Box 360
Yavne 70650
ISRAEL
Contact: Rosanne Tzuk, Export Manager
Tel: +972 8 9429201
Fax: +972 8 9438758
E-mail: **rosanne@orgenics.co.il**
URL: **http://www.orgenics.com**

Genie II HIV-1/HIV-2
BIO-RAD
Clinical Diagnostics
3 Boulevard Raymond Poincare
92430 Mones La Coquette
FRANCE
Contact: Amina Khelaf
Phone: +33-1-4795-6018
Fax: +33-1-4795-6186
E-mail: **amina_khelaf@bio-rad.com**
URL: **http://www.bio-rad.com**

Hema•Strip™ HIV
Chembio Diagnostics Systems, Inc.
3661 Horseblock Road
Melford, NY 11763
USA
Contact: Avi Pelossof, Director of Sales & Marketing
Phone: +1-631-924-1135
Fax: +1-631-924-6033
E-mail: **avi@chembio.com** or **info@salv.com**
URL: **http://www.salv.com** or **www.chembio.com**

HIV SPOT™ – discontinued[1]
Genelabs Diagnostics Pte Ltd
85 Science Park Drive
#04-01, The Cavendish
Singapore Science Park
SINGAPORE 118259
Phone: +65-775-0008
Fax: +65-774-6146
E-mail: **genelabs@pacific.net.sg**
URL: **http://www.genelabs.com.sg**

[1] HIV SPOT™ has been discontinued according to information received January 2002 from Genelabs Diagnostics Pte Ltd, the manufacturer.

OR
Genelabs Diagnostics Inc
505 Penobscot Drive
Redwood City, CA 94063
USA
Phone: +1-650-369-9500
Fax: +1-650-369-6154
E-mail: **jwonglee@genelabs.com**

HIV*Sav* 1&2 Rapid SeroTest™
Sayvon Diagnostics Ltd.
3 Habosem St.
Ashdod 77610
ISRAEL
Contact: Elana Bitton
Telephone: +972 8 856 2929 Ext. 202
Fax: +972 8 852 3176
E-mail: **elana@savyon-d.co.il**
URL: **www.hctech.com/savyon**

Multispot HIV-1/HIV-2
Bio-Rad Laboratories
Clinical Diagnostics
3 Boulevard Raymond Poincare
92430 Mones La Coquette
FRANCE
Contact: Amina Khelaf
Phone: +33-1-4795-6018
Fax: +33-1-4795-6186
E-mail: **amina_khelaf@bio-rad.com**
URL: **http://www.bio-rad.com**

SeroCard™ HIV
Trinity Biotech Plc
IDA Business Park
Bray, Co Wicklow
IRELAND
Contact: Marie McCarthy, Group Product Manager
Phone: +353-1-276-9828
Fax: +353-1-276-9881
E-mail: **mmcarthy@trinitybiotech.ie**
or **info@trinitybiotech.ie**
URL: **http://trinitybiotech.com**

Sero•Strip™ HIV
Chembio Diagnostics Systems, Inc.
3661 Horseblock Road
Melford, NY 11763
USA
Contact: Avi Pelossof, Director of Sales & Marketing
Phone: +1-631-924-1135
Fax: +1-631-924-6033
E-mail: **avi@chembio.com** or **info@salv.com**
URL: **http://www.salv.com** or **www.chembio.com**

SUDS HIV-1
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064
USA
Contact: Friedah Nehmadi
Phone: +1-847-935-8771
Fax: +1-847-937-0912
E-mail: **friedah.nehmadi@abbott.com**
URL: **http://www.abbottdiagnostics.com**

Annex 12
Useful Contacts

Useful Contacts

CDC – U.S. Centers for Disease Control and Prevention

For information on HIV test kits including evaluations of specific test kits, sensitivity, specificity and HIV variants detected, evaluation of country HIV testing algorithms where CDC has assisted in the design of the algorithm, contact—

Dr Mark Rayfield
E-mail: **MRayfield@cdc.gov**

FDA – U.S. Food and Drug Administration

For information on FDA approval information on drug products, contact—

CDER - FDA Center for Drug Evaluation and Research

Phone: +1-301-827-4570
Email: **druginfo@cder.fda.gov**

For information on FDA approval information on biological products including vaccines and HIV test kits, contact—

CBER - FDA Center for Biologics Evaluation and Research

Phone: +1-301-827-1800 or 1-800-835-4709
Email: **octma@cber.fda.gov**

PhRMA – Pharmaceutical Research and Manufacturers of America

For contact information for pharmaceutical manufacturers—

Email: **www.phrma.org/membership/memlist.html**

WHO – World Health Organization

WHO periodically evaluates ELISAs and HIV test kits that are available for bulk purchase by the public sector. Results of these evaluations are available in Comparative Evaluation of the Operational Characteristics of Commercially Available Assays to Detect Antibodies to HIV-1 and/or HIV-2 in Human Sera.

Table 1 contains information on HIV Antibody ELISA tests and is available from **www.who.int/pt/blood_safety/hivtable1.html**.

Table 2 contains information on HIV test kits and is available from **www.who.int/pt/blood_safety/hivtable2.html**.

For information on availability of HIV test kits from WHO through the WHO bulk procurement scheme, contact—

Mrs. Helen Scaramuzzi

World Health Organization Procurement Services
Phone: +4122-791-21-80
Fax: +4122-791-41-96
E-mail: **scaramuzzih@who.ch**

Annex 13
2001 *Drug Topics*® *Red Book*®
Pharmaceutical Wholesaler Directory

PHARMACEUTICAL WHOLESALER DIRECTORY

The following is an alphabetical listing of pharmaceutical wholesalers in the United States and Puerto Rico. The names, addresses, and phone numbers typically represent headquarters locations. Regional office information is available through these main offices.

ADRIANA DISTRIBUTORS, INC.
107 El Tuque Industrial Park
Ponce, PR 00731
787-284-3000
800-981-9535
Fax: 787-284-4000

AMERICAN MEDICAL SERVICES, INC.
300 N. Elizabeth
4th Floor East
Chicago, IL 60607
312-432-0250
Fax: 312-432-0295

AMERISOURCE CORP.
300 Chester Field Pkwy.
Malvern, PA 19355
610-296-4480
Fax: 610-647-0141
www.amerisource.com

ANDA INC.
2915 Weston Rd.
Weston, FL 33331
800-331-2632
Fax: 954-217-4378
www.andrx.com

J. J. BALAN, INC.
5725 Foster Ave.
Brooklyn, NY 11234
718-251-8663
800-JJBalan
Fax: 718-251-0024
www.jjbalan.com

BARNES WHOLESALE DRUG, INC.
740 Glasgow Ave.
Inglewood, CA 90301
310-641-1885
800-227-4845
Fax: 310-645-7862
www.barneswholesale.com

BECAN DISTRIBUTORS, INC.
Subsidiary of drugmax.com
203 Parkway View Dr.
Pittsburgh, PA 15205
412-490-4980
888-892-3226
Fax: 412-490-4985

BELLAMY DRUG CO./KING DRUG CO. OF FLORENCE, INC.
411 Landmark Dr.
Wilmington, NC 28412
910-799-3320
800-800-8748
Fax: 910-791-3248

BELLCO DRUG CORP.
101 East Hoffman Ave.
Lindenhurst, NY 11757-5057
516-226-3500
Fax: 516-226-3594
www.bellcocorp.com

BERGEN BRUNSWIG CORP.
4000 Metropolitan Dr.
Orange, CA 92868
714-385-4000
Fax: 714-385-1442
www.bergenbrunswig.com

BINDLEY WESTERN INDUSTRIES, INC.
8909 Purdue Rd.
Indianapolis, IN 46268
317-704-4000
Fax: 317-704-4612
www.bindley.com

J.M. BLANCO, INC.
Diana St. #21
Amelia Industrial Park
Guaynabo, PR 00968
787-793-6262
Fax: 787-273-2160

BORSCHOW DRUG
Calaf St. &
Las Americas Expressway
Tres Monjitas Industry Park
Hato Rey, PR 00918
787-754-2300
Fax: 787-250-4658
www.Borschow.com

JAMES BRUDNICK CO., INC.
219 Medford St.
Malden, MA 02148
781-321-6800
Fax: 781-397-9576

BURLINGTON DRUG CO.
91 Catamount Dr.
Milton, VT 05468-1001
802-893-5105
Fax: 802-893-5110

CAPITAL WHOLESALE DRUG CO.
873 Williams Ave.
Columbus, OH 43212
614-297-8225
Fax: 614-297-8224

CARDINAL HEALTH, INC.
7000 Cardinal Pl.
Dublin, OH 43017
614-757-5000
Fax: 614-757-6000
www.cardhealth.com

CHAPIN MEDICAL CO.
423 Jenks Circle
Corona, CA 92880
909-735-5300
800-221-7180
Fax: 909-735-6117
www.chapinmedical.com

D&K HEALTH CARE RESOURCES, INC.
8000 Maryland Ave.
Suite 920
St. Louis, MO 63105-3752
314-727-3485
888-727-3485
Fax: 314-727-5759
www.dkwd.com

DAKOTA DRUG, INC.
28-32 North Main St.
Minot, ND 58703-5009
701-852-2141
Fax: 701-857-1134

DARBY DRUG CO.
865 Merrick Ave.
Westbury, NY 11590
516-683-1800
Fax: 516-832-8775
www.darbydrug.com

DDN/OBERGFEL, LLC
N114 W 18850 Clinton Dr.
Germantown, WI 53022
414-250-5067
Fax: 414-250-5062

DIK DRUG CO.
160 Tower Dr.
Burr Ridge, IL 60521
630-655-4000
Fax: 630-655-4031

DIVERSIFIED HEALTH CARE, INC. (DHI)
420 Northwest Fifth St.
Evansville, IN 47708-0869
812-428-6700
Fax: 812-428-6790
www.dhiinc.com

DIXON-SHANE DRUG CO.
256 Geiger Rd.
Philadelphia, PA 19115
215-673-3415
800-262-7770
Fax: 215-673-3445
www.dixonshane.com

DMS PHARMACEUTICAL GROUP
810 Busse Hwy.
Park Ridge, IL 60068
847-518-1100
Fax: 847-518-1105

THE F. DOHMEN CO.
W194 N11381 McCormick Dr.
Germantown, WI 53022
262-255-0022
800-444-4496
Fax: 262-255-0041

DROGUERIA BETANCES, INC.
Reparto Industrial Park
Carr #1 Km 34.4
Caguas, PR 00726
787-746-0951
Fax: 787-744-7773

FMC DISTRIBUTORS, INC.
Ave Stgo De Los Caballero
Ponce, PR 00732
787-841-8181
800-980-3527
Fax: 787-841-8184
www.fmcpr.com

G & G DRUG WHOLESALERS, INC.
160 Dupont St.
Plainview, NY 11803
800-966-8282
Fax: 800-966-4439

GENERAL DRUG CO.
200 North Fairfield Ave.
Chicago, IL 60612-2088
773-826-4242
Fax: 773-826-6231

MANUFACTURER/WHOLESALER INFORMATION 113

GENERICS OF P.R., INC.
Calle Acacia #3
Urb. Monte Rey
Pueblo Viejo, PR 00920
787-792-2430
Fax: 787-782-0990
generics@prcinternet.net

GOODWIN DRUG CO.
1410 Main St.
Wheeling, WV 26003
304-233-0260
Fax: 304-233-1870

HARVARD DRUG GROUP
31778 Enterprise Dr.
Livonia, MI 48150
734-525-8700
800-875-0123
Fax: 734-525-8393

HENRY SCHEIN, INC.
135 Duryea Rd.
Melville, NY 11747
516-843-5500
Fax: 516-390-8126
www.henryschein.com

JEWETT DRUG CO.
217 Railroad Ave. SE
Aberdeen, SD 57401
605-225-0870
800-535-0297
Fax: 605-225-0591

FRANK W. KERR CO.
43155 West Nine Mile Rd.
Novi, MI 48376
248-349-5000
Fax: 248-374-6060
www.fwkerr.com

KING DRUG CO. OF FLORENCE
605 West Lucas St.
Florence, SC 29501-2823
843-662-0411
800-922-9597
Fax: 843-662-0414

KINRAY INC.
152-35 10th Ave.
Whitestone, NY 11357-1123
718-767-1234
800-854-6729
Fax: 718-767-4706
www.kinray.com

LOUISIANA WHOLESALE DRUG CO., INC.
2085 I-49 S Service Rd.
Sunset, LA 70584
318-662-1040
800-960-3784
Fax: 318-662-5784

M-D OF BEAUMONT
Allen Dickson, Inc.
410 Kay Lane
Shreveport, LA 71135
409-296-6969
Fax: 409-296-9491

MCKESSON HBOC, INC.
One Post St.
San Francisco, CA 94104
415-983-8300
Fax: 415-983-8826
www.mckesson.com

MCQUEARY BROS. DRUG CO.
500 West Olive
Springfield, MO 65806
417-869-2577
Fax: 417-831-5207

MEDSOURCE CORP.
2100 Patridge Rd.
Dewey, OK 74029
918-534-1210
800-256-2828
Fax: 918-534-1314

MENCAR PHARMACEUTICAL CORP.
67 West Easy St. #117
Simi Valley, CA 93065
805-584-8092
Fax: 805-584-8196

METRO MEDICAL SUPPLY WHOLESALE, INC.
3332 Powell Ave.
Nashville, TN 37204
615-329-2002
Fax: 615-256-4194

MIAMI-LUKEN, INC.
265 Pioneer Blvd.
Springboro, OH 45066
513-743-7775
Fax: 513-743-7786

MORRIS & DICKSON CO., LTD.
410 Kay Lane
Shreveport, LA 71115
318-797-7900
Fax: 318-798-6007
www.morrisdickson.com

M. SOBOL, INC.
Sub. of Allou Health & Beauty
50 Emjay Blvd.
Brentwood, NY 11717
516-231-7733
800-697-6265
Fax: 516-787-1389

N.C. MUTUAL WHOLESALE DRUG CO.
816 Ellis Rd.
Durham, NC 27703-9979
919-596-2151
Fax: 919-596-1453

P.D.I. ENTERPRISES, INC.
26245 Technology Dr.
Valencia, CA 91355-1147
805-294-8200
800-424-6321
Fax: 805-294-8228

PENNER & WELSCH, INC.
802 Short St., Building J
Kenner, LA 70062
504-471-0945
Fax: 504-471-0909

PHARMED GROUP CORP.
3075 NW 107th Ave.
(Pharmed Way)
Miami, FL 33172
305-592-2324
800-683-7342
Fax: 305-591-9643
www.pharmed.com

PRESCRIPTION SUPPLY, INC.
2233 Tracy Rd.
Northwood, OH 43619-1326
419-661-6600
800-777-0761
Fax: 419-661-6617

QUALITY KING DISTRIBUTORS, INC.
2060 Ninth Ave.
Ronkonkoma, NY 11779
516-737-5555
800-676-5554
Fax: 516-439-2344
www.qkd.com

R & S SALES, INC.
8407 Austin Tracy Rd.
Fountain Run, KY 42133
270-434-2045
800-626-0208
Fax: 270-434-2880

REBEL DISTRIBUTORS CORP.
31238 Via Colinas, Unit D
Westlake Village, CA 91362
818-865-6880
888-870-6880
Fax: 818-865-6885
www.rebelrx.com

REMO DRUG CORP.
315 East 89th St.
Brooklyn, NY 11236-9978
718-272-8213
Fax: 718-272-0893
www.remodrug.com

RESPIRATORY DISTRIBUTORS, INC.
110 East Azalea Ave.
Foley, AL 36535
334-943-5844
800-872-8672
Fax: 800-891-8671
www.rrdi.com

ROCHESTER DRUG COOPERATIVE
320 North Goodman St.
Rochester, NY 14603
716-271-7220
800-333-0538
Fax: 716-271-3551
www.rdcdrug.com

H.D. SMITH WHOLESALE DRUG CO.
4650 Industrial Dr.
Springfield, IL 62703
217-529-0211
Fax: 217-529-1546
www.hdsmith.com

SMITH DRUG CO.
Div. JM Smith Corp.
450 Wofford St.
Spartanburg, SC 29301
864-582-1218
Fax: 864-591-0333

SMITH MEDICAL PARTNERS
960 Lively Blvd.
Wood Dale, IL 60191
630-227-9420
800-292-9653
Fax: 630-227-9220

SUPERIOR PHARMACEUTICAL CO.
1385 Kemper Meadow Dr.
Cincinnati, OH 45240-1635
513-851-3600
800-826-5035
Fax: 513-742-6473
www.superiorpharm.com

SUPREME DISTRIBUTORS CO.
5400 Broken Sound Blvd. NW
Suite 100
Boca Raton, FL 33487
561-994-9630
800-323-6838
Fax: 561-994-9576

TEXAS DRUG CO.
Subsidiary of H.D. Smith Wholesale Drug Co.
1101 West Vickery Blvd.
Fort Worth, TX 76104
817-335-5761
888-378-4668
Fax: 817-334-0310

VALLEY DRUG CO.
318 West Boardman St.
Youngstown, OH 44503
330-744-0283
Fax: 330-744-2822

VALLEY WHOLESALE DRUG CO.
1401 West Fremont St.
Stockton, CA 95203-2697
209-466-0131
800-247-6255
Fax: 209-465-4056

VALUE DRUG CO.
One Golf View Dr.
Altoona, PA 16601
814-944-9316
800-252-3786
Fax: 814-944-9553

WALSH DISTRIBUTION, INC.
5005 North State Line
Texarkana, TX 75503
903-794-5141
Fax: 903-735-4047
www.walshdist.com

WHOLESALEPHARMACY.COM, INC.
301 North Charles St.
Suite 403
Baltimore, MD 21201
410-625-9007
Fax: 410-625-9133
www.wholesalepharmacy.com